MCCAIN) was added as a cosponsor of S. 407, a bill to restore health care coverage to retired members of the uniformed services, and for other purposes.

S. 424

At the request of Mr. BOND, the names of the Senator from Washington (Mrs. MURRAY) and the Senator from Maryland (Ms. MIKULSKI) were added as cosponsors of S. 424, a bill to amend the Public Health Service Act to provide for arthritis research and public health, and for other purposes.

S. 427

At the request of Mr. JEFFORDS, the name of the Senator from New York (Mr. SCHUMER) was added as a cosponsor of S. 427, a bill to amend the Public Utility Regulatory Policies Act of 1978 to provide for a Federal renewable portfolio standard.

S. 438

At the request of Mr. ENSIGN, the names of the Senator from Michigan (Ms. STABENOW) and the Senator from Washington (Ms. CANTWELL) were added as cosponsors of S. 438, a bill to amend title XVIII of the Social Security Act to repeal the medicare outpatient rehabilitation therapy caps.

S.J. RES. 4

At the request of Mr. CONRAD, the name of the Senator from Oregon (Mr. WYDEN) was added as a cosponsor of S.J. Res. 4, a joint resolution providing for congressional disapproval of the rule submitted by the Department of Agriculture under chapter 8 of title 5, United States Code, relating to risk zones for introduction of bovine spongiform encephalopathy.

S. RES. 39

At the request of Ms. LANDRIEU, the names of the Senator from Maryland (Mr. SARBANES) and the Senator from Massachusetts (Mr. KERRY) were added as cosponsors of S. Res. 39, a resolution apologizing to the victims of lynching and the descendants of those victims for the failure of the Senate to enact anti-lynching legislation.

S. RES. 55

At the request of Mr. GRAHAM, the name of the Senator from Louisiana (Ms. LANDRIEU) was added as a cosponsor of S. Res. 55, a resolution recognizing the contributions of the late Zhao Ziyang to the people of China.

S. RES. 59

At the request of Mr. SMITH, the name of the Senator from North Carolina (Mrs. DOLE) was added as a cosponsor of S. Res. 59, a resolution urging the European Union to maintain its arms export embargo on the People's Republic of China.

STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

By Mr. AKAKA (for himself, Mr. SARBANES, and Mr. CORZINE):

S. 468. A bill to amend the Higher Education Act of 1965 to enhance the literacy in finance and economics, and for other purposes; to the Committee on Health, Education, Labor, and Pensions.

Mr. AKAKA. Mr. President, I rise to reintroduce comprehensive legislation aimed at addressing the issue of economic and financial illiteracy on college campuses. I am referring to the worrisome problems of skyrocketing debt levels, low rates of saving, and the proliferation of unchecked predatory practices by unscrupulous financial institutions among young adults who hold our country's future in their hands. Entitled the College LIFE or College Literacy In Finance and Economics Act, this bill has the support of Senators SARBANES and CORZINE. I thank my colleagues from Maryland and New Jersey for joining me as original cosponsors of this measure. I also thank Senator ENZI, the Chairman of the Health, Education, Labor, and Pensions Committee, for working with me on financial literacy as it affects all constituencies, including college students.

The problem we are working to address with the College LIFE Act is simple. Our college students are many of America's best and the brightest and will go on to become leaders—in business, education, politics, the military, the community—any area you can name. I find it wonderful that many young people are fulfilling their dreams of higher education in numbers that I did not imagine when I was in college. In fact, as reported by the Census Bureau, college enrollment was estimated at 15.9 million for the current school year, compared to 5.7 million in 1965 when the Higher Education Act was enacted. However, I am gravely concerned, both as a member of this body and particularly as a grandparent and great-grandparent, that our young people are entering college without proper direction or good skills for money management or economic decisionmaking.

As we work on increasing access to higher education, we must give students access to tools needed to make sound economic and financial decisions once they are on campus; however, the lack of personal finance and economics standards or implementation of existing standards in elementary and secondary education in a number of States results in many students arriving at college with little understanding of economic concepts like supply and demand or benefits versus costs, or personal finance concepts such as household money management or the importance of maintaining good credit history. Without this basic understanding, college students are not effectively evaluating credit alternatives, managing their debt, and preparing for long-term financial goals, such as saving for a home or retirement.

Imagine life from the point of view of a college student. A young adult leaves his home and travels many miles—thousands of miles in the case of Hawaii students attending mainland colleges—to the campus that holds his hopes and dreams. Perhaps he is not being mindful of how much money he needs for textbooks, school supplies, or student fees. He visits the campus bookstore and walks out with a bag that includes a preapproved credit card application, which he immediately completes and sends. Months later, he has joined other credit card-holding college students who, on average, have credit card balances above $3,000. Sophomore year rolls around and, instead of conferring with his parents about the details of his renewal FAFSA for student financial aid or master promissory note, he is saddled with another $20,000 loan. According to the Census Bureau, average college tuition, room, and board have increased to $29,119 for a four-year private institution and to $9,953 for a four-year public institution. The same scenario repeats itself in junior and senior year. Finally, after completing all coursework, he graduates, finds an entry-level job, and realizes that, after servicing his debt, he has little left to spend on basics such as food, transportation, and rent, much less career clothing or a new briefcase. His lack of knowledge about how to properly use credit has led him to anxiety-causing financial missteps. With appropriate financial and economic literacy, he may have known what debt load to anticipate and made wiser financing and spending decisions while in school.

Instead, she may be on the road to true financial trouble. A U.S. Public Interest Research Group and Consumer Federation of America analysis of Federal Reserve data indicates that the average household with debt carries approximately $10,000 to $12,000 in total revolving debt and has nine credit cards. From January through September of 2004, approximately 1.2 million consumers filed for bankruptcy, keeping pace with last year's record level, which is almost half of the number of college diplomas expected to be conferred this year at 2.5 million. Furthermore, the Federal Reserve Board reports that Americans currently pay more than 13 percent of after-tax income to service their debts. We must ensure that our youth make the right decisions to follow a better financial path. This is especially in light of a report cited by Dan Iannicola, Jr., Deputy Assistant Secretary of the Treasury for Financial Education, at a House hearing last Congress, noting that youths spent more than $172 billion in a recent year, and figures from MarketResearch.com noting that typical 8- to 14-year-olds spend—from allowances, jobs, and gifts—nearly $1,300 a year or $25 a week.

The College LIFE Act represents a comprehensive approach to assist upcoming generations of Americans. It proposes four new grant programs that provide resources to encourage experimentation with delivery systems—innovative methods used in or out of the classroom to increase college students'

financial literacy. Another grant would allow higher education institutions to share best practices about or create personal finance courses where none exist. A third grant would assist efforts that are looking at the best ways to integrate personal finance and economic education into basic educational subjects, which is especially important as schools are facing challenges under the No Child Left Behind Act and are tempted to focus on subjects being tested for Adequate Yearly Progress. The final grant would train teachers and high school counselors toward increasing financial and economic literacy in grades K–12 so that our college students are prepared when they arrive at college campuses.

The bill also proposes a pilot program for five higher education institutions to encourage students to take a personal finance course and participate in preventive annual credit counseling, working in conjunction with State or local public, private, and nonprofit entities selected by the local education agency or the school, and measuring the effectiveness of efforts in any behavioral changes that may result. It promotes greater collaboration with and support from Federal agencies in the form of the Financial Literacy and Education Commission. Finally, the measure emphasizes the importance of personal finance and economic education and counseling by authorizing these activities as allowable uses in existing Higher Education Act programs, such as TRIO, GEAR UP, and Title III and Title V Serving Institutions.

Furthermore, I intend the reach of this bill to be beyond the traditional college student. Our returning college students are a vital part of society—many who are already community leaders and breadwinners for their families who have already gained valuable work experience that they may use as they learn a new field or continue their undergraduate study in the pursuit of a graduate or doctoral degree. In addition, older adults who are entering higher education for the first time can also be lauded for their enterprising spirit in wanting to better their lives by earning an associates or bachelors degree. I anticipate that the assistance provided through the College LIFE Act will work to provided needed help to many of these students as well.

I am looking forward to continuing to work with my colleagues to have the College LIFE Act passed or included in the upcoming Higher Education Act reauthorization. I encourage my colleagues' support for this bill.

By Mr. ROCKEFELLER (for himself, Mr. LOTT, Mr. ROBERTS, Ms. SNOWE, Mr. BAYH, Mr. CHAMBLISS, Ms. MIKULSKI, Mr. CORZINE, Mr. LEVIN, Mr. DEWINE, Mr. WYDEN, Mr. BOND, Mrs. FEINSTEIN, Mr. HAGEL, and Mr. HATCH):

S. 469. A bill to amend the Internal Revenue Code of 1986 to exclude from gross income the gain from the sale of a principal residence by certain employees of the intelligence community; to the Committee on Finance.

Mr. ROCKEFELLER. Mr. President, today I am introducing legislation to extend an important tax benefit to the men and women of the United States Intelligence Community. I am pleased that in keeping with the bipartisan traditions of the Intelligence Committee, every member, Republican and Democrat, is listed as an original cosponsor.

Two years ago, on Veterans Day, President Bush signed into law an important modification to our tax code to ensure that it does not punish those who serve our country in the military and in the U.S. foreign service. Unfortunately, that legislation did not extend to intelligence officers, who serve alongside their military and diplomatic colleagues all around the world and who often face the same tax issues encountered by those individuals. The legislation I am introducing today makes a common sense modification to the capital gains tax exclusion rules to ensure that when selling their homes, intelligence officers do not pay more tax than they would if they did not serve their country.

The men and women of the Intelligence Community, serve with the military in Iraq, Afghanistan, Korea, and numerous other locations where we have U.S. forces deployed. They also serve in U.S. Embassies around the world. Often times they carry an added burden because they must serve undercover. Their families and friends don't know what they do. They live their cover story by day and perform their critical intelligence work by night. They work for all fifteen of the agencies included in the intelligence community and they do a remarkable job. These people are dedicated to their mission and to this country.

These patriotic individuals sacrifice a great deal on behalf of the rest of us. They uproot and relocate their families every few years. They often live in places most of us wouldn't even visit. And they rarely have the quality of life with access to modern luxuries that the rest of us take for granted. To then say that they are going to be penalized by our tax code is unacceptable.

Since 1997, our tax code has allowed Americans to sell their homes without paying taxes on up to $250,000 of capital gains. Married couples can exclude $500,000 in capital gains from taxation. This provision is specifically intended only for principle residences, and therefore, sellers are required to have lived in the homes for at least 2 of the 5 years prior to sale.

In 2003, Congress recognized that this residency requirement was often difficult for members of the armed forces and foreign service to satisfy. If they had been stationed away from home while serving their country, they were essentially punished with higher taxes on the sales of their homes. Congress addressed this injustice by allowing service personnel and foreign service officers who were stationed away from home to suspend the residency requirement for as many as ten years. This change allows, for example, a soldier who spent the last 7 years stationed in Germany to exclude from taxes the capital gains on the sale of his former home in the U.S., as long as he had lived in it for at least 2 of the 5 years prior to his service overseas. The change is effective on all sales after 1997, when the capital gains tax exclusion for home sales was provided to all Americans.

Fairness demands that Congress apply the same rules to intelligence officers serving their country away from home. My legislation simply inserts intelligence officers into the list of those allowed to suspend the 5 year residency test period for up to 10 years while they are stationed away from home.

I intend to work with my colleagues on the Intelligence Committee and the Finance Committee to ensure that this provision is enacted this year.

By Mr. DODD (for himself, Mr. GRASSLEY, Mr. JOHNSON, and Mr. WYDEN):

S. 470. A bill to amend the Public Health Service Act to expand the clinical trials drug data bank; to the Committee on Health, Education, Labor, and Pensions.

Mr. DODD. Mr. President, I rise today to introduce the Fair Access to Clinical Trials, FACT, Act. I want to begin by thanking Senator GRASSLEY, Senator JOHNSON, and Senator WYDEN for joining me in introducing this legislation. Our bill will create an electronic databanks for clinical trials of drugs, biological products, and medical devices. Such a databank will ensure that physicians, researchers, the general public, and patients seeking to enroll in clinical trials have access to basic information about those trials. It will require manufacturers and other researchers to reveal the results of clinical trials so that clinically important information will be available to all Americans, and physicians will have all the necessary information to make appropriate treatment decisions for their patients.

Events of the past year have made it clear that such a databank is needed. First, serious questions were raised about the effectiveness and safety of antidepressants when used in children and youth. It has now become clear that the existing data indicates that these drugs may very well put children at risk. However, because the data from antidepressant clinical trials was not publicly available, it took years for this risk to be realized. In the meantime, millions of children have been prescribed antidepressants by well-meaning physicians. While these drugs undoubtedly helped many of these children, they also led to greater suffering for others. Recently, it has been suggested that the risk of antidepressants might even extend beyond children.

The news is similarly disturbing for a popular class of painkillers known as Cox–2 inhibitors. These medicines, taken by millions of Americans, have been associated with an increased risk of cardiovascular adverse events, such as heart attack and stroke. It has been suggested that one of these medicines, which has since been pulled from the market, may be responsible for tens of thousands of deaths.

Unfortunately, antidepressants and Cox–2 inhibitors are just two examples of a story that has become all too common. It has been suggested that negative data might actually have been suppressed; and if this is discovered to be the case, those responsible should be dealt with harshly. However, because of what is known as ''publication bias,'' the information available to the public and physicians can be misleading even without nefarious motives. The simple fact is that a study with a positive result is far more likely to be published, and thus publicly available, than a study with a negative result. Physicians and patients hear the good news, but rarely the bad news. In the end, the imbalance of available information hurts patients.

Our bill would correct the imbalance of information, and prevent manufacturers from suppressing negative data. It would do so by creating a two-part databank, consisting of an expansion of clinicaltrials.gov—an existing registry that is operated by the National Library of Medicine, NLM—and a new database for clinical trial results.

Under the FACT Act, the registry would continue to operate as a resource for patients seeking to enroll in clinical trials for drugs and biological products intended to treat serious or life-threatening conditions—and for the first time, it would also include medical device trials. The new results database would include all trials, except for preliminary safety trials, and would require the submission of results data.

Our legislation would enforce the requirement to submit information to the databank in two ways. First, by requiring registration as a condition of Institutional Review Board, IRB, approval, no trial could begin without submitting preliminary information to the registry and database. This information would include the purpose of the trial, the estimated date of trial completion, as well as all of the information necessary to help patients to enroll in the trial.

Once the trial is completed, the researcher or manufacturer would be required to submit the results to the database. If they refuse to do so, they would be subject to monetary penalties or, in the case of federally funded research, a restriction on future funding. It is my belief that these enforcement mechanisms will ensure broad compliance. However, in the rare case where a manufacturer does not comply, this legislation also gives the Food and Drug Administration, FDA, the authority to publicize the required information.

Let me also say that any time you are collecting large amounts of data and making it public, protecting patient privacy and confidentiality must be paramount. Our legislation would in no way threaten that privacy. The simple fact is that under this bill, no individually identifiable information would be available to the public.

I believe that the establishment of a clinical trials databank is absolutely necessary for the health and well-being of the American public. But I would also like to highlight two other benefits that such a databank will have. First, it has the potential to reduce health care costs. Studies have shown that publication bias also leads to a bias toward new and more expensive treatment options. A databank could help make it clear that, in some cases, less expensive treatments are just as effective for patients.

In addition, a databank will ensure that the sacrifice made by patients who enroll in clinical trials is not squandered. Many patients would be less willing to participate in trials if they understood that the data are unlikely to be made public if the results of the trial are negative. We owe it to patients to make sure that their participation in a trial will benefit other individuals suffering from the same illness or condition.

The problems associated with publication bias have recently drawn more attention from the medical community, and there is broad consensus that a clinical trials registry is one of the best ways to address the issue. Accordingly, the American Medical Association, AMA, has recommended the creation of such a databank, and the major medical journals have established a policy that they will only publish the results of trials that were registered in a public database before the trial began. Our legislation meets all of the minimum criteria for a trial registry set out by the International Committee of Medical Journal Editors.

To its credit, the pharmaceutical industry has also acknowledged the problem, and has created a database to which manufacturers can voluntarily submit clinical trials data. I applaud this step. However, if our objective is to provide the public with a complete and consistent supply of information, a voluntary database is unlikely to achieve that goal. Some companies will provide information, but others may decide not to participate. We need a clinical trials framework that is not just fair to all companies, but provides patients with peace of mind that they will receive complete information about the medicines they rely on.

The American drug industry is an extraordinary success story. As a result of the innovations that this industry has spawned, millions of lives have been improved and saved in our country and around the globe. Because of the importance of these medicines to our health and well-being, I have consistently supported sound public policies to help the industry to succeed. This legislation aims to build upon the successes of this industry, and help ensure that the positive changes to our health care system that prescription drugs have brought are not undermined by controversies such as the ones now surrounding antidepressants and Cox-2 inhibitors, which are at least in part based on a lack of public information. This bill will help ensure that well-informed patients will use new and innovative medicines.

I look forward to working with industry, physicians, the medical journals, patient groups, and my colleagues—including the Chairman and the Ranking Member of the Health, Education, Labor, and Pensions Committee, Senator ENZI and Senator KENNEDY—to move this legislation forward. This bill has already been endorsed by the National Organization for Rare Disorders, Consumers Union, the Elizabeth Glaser Pediatric AIDS Foundation, the American Academy of Child and Adolescent Psychiatry, the American Psychiatric Association, the New England Journal of Medicine, and the National Women's Health Network. I thank these organizations for lending their expertise as we crafted this legislation.

The creation of a clinical trials databank is a critical step toward ensuring the safety of drugs, biological products, and devices in this country—but it should not be the end of our efforts. I believe that other steps are necessary to fully restore patient confidence in the safety of the medicines they rely on. I have already announced my intention to introduce another piece of legislation that will create an Office of Patient Protection within the FDA, which will be responsible for ensuring the safety of prescription drugs once they are on the market. I look forward to introducing this bill in the coming weeks.

Clinical trials are critical to protecting the safety and health of the American public, and for this reason, trial results must not be treated as information that can be hidden from scrutiny. Recent events have made it clear that a clinical trials databank is needed. Patients and physicians agree that such a databank is in the interest of the public health. I urge my colleagues to support this legislation, and I am hopeful that it will become law as soon as possible.

I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the bill was ordered to be printed in the RECORD, as follows:

S. 470

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Fair Access to Clinical Trials Act of 2005'' or the ''FACT Act''.

SEC. 2. PURPOSE.

It is the purpose of this Act—

(1) to create a publicly accessible national data bank of clinical trial information comprised of a clinical trial registry and a clinical trial results database;

(2) to foster transparency and accountability in health-related intervention research and development;

(3) to maintain a clinical trial registry accessible to patients and health care practitioners seeking information related to ongoing clinical trials for serious or life-threatening diseases and conditions; and

(4) to establish a clinical trials results database of all publicly and privately funded clinical trial results regardless of outcome, that is accessible to the scientific community, health care practitioners, and members of the public.

SEC. 3. CLINICAL TRIALS DATA BANK.

(a) IN GENERAL.—Section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)) is amended—

(1) in paragraph (1)(A), by striking ''for drugs for serious or life-threatening diseases and conditions'';

(2) in paragraph (2), by striking ''available to individuals with serious'' and all that follows through the period and inserting ''accessible to patients, other members of the public, health care practitioners, researchers and the scientific community. In making information about clinical trials publicly available, the Secretary shall seek to be as timely and transparent as possible.'';

(3) by redesignating paragraphs (4) and (5), as paragraphs (8) and (9), respectively;

(4) by striking paragraph (3) and inserting the following:

''(3) The data bank shall include the following:

''(A)(i) A registry of clinical trials (in this subparagraph referred to as the 'registry') of health-related interventions (whether federally or privately funded).

''(ii) The registry shall include information for all clinical trials conducted to test the safety or effectiveness (including comparative effectiveness) of any drug, biological product, or device (including those drugs, biological products, or devices approved or cleared by the Secretary) intended to treat serious or life-threatening diseases and conditions, except those Phase I clinical trials conducted to test solely the safety of an unapproved drug or unlicensed biological product, or pilot or feasibility studies conducted to confirm the design and operating specifications of an unapproved or not yet cleared medical device. For purposes of this section, Phase I clinical trials are trials described in section 313.12(a) of title 21, Code of Federal Regulations (or any successor regulations).

''(iii) The registry may include information for—

''(I) Phase I clinical trials conducted to test solely the safety of an unapproved drug or unlicensed biological product, or pilot or feasibility studies conducted to confirm the design and operating specifications of an unapproved or not yet cleared medical device with the consent of the responsible person; and

''(II) clinical trials of other health-related interventions with the consent of the responsible person.

''(iv) The information to be included in the registry under this subparagraph shall include the following:

''(I) Descriptive information, including a brief title, trial description in lay terminology, trial phase, trial type, trial purpose, description of the primary and secondary clinical outcome measures to be examined in the trial, the time at which the outcome measures will be assessed, and the dates and details of any revisions to such outcomes.

''(II) Recruitment information, including eligibility and exclusion criteria, a description of whether, and through what procedure, the manufacturer or sponsor of the investigation of a new drug will respond to requests for protocol exception, with appropriate safeguards, for single-patient and expanded protocol use of the new drug, particularly in children, a statement as to whether the trial is closed to enrollment of new patients, overall trial status, individual site status, and estimated completion date. For purposes of this section the term 'completion date' means the date of the last visit by subjects in the trial for the outcomes described in subclause (I).

''(III) Location and contact information, including the identity of the responsible person.

''(IV) Administrative data, including the study sponsor and the study funding source.

''(V) Information pertaining to experimental treatments for serious or life threatening diseases and conditions (whether federally or privately funded) that may be available—

''(aa) under a treatment investigational new drug application that has been submitted to the Secretary under section 360bbb(c) of title 21, Code of Federal Regulations; or

''(bb) as a Group C cancer drug (as defined by the National Cancer Institute).

''(B)(i) A clinical trials results database (in this subparagraph referred to as the 'database') of health-related interventions (whether federally or privately funded).

''(ii) The database shall include information for all clinical trials conducted to test the safety or effectiveness (including comparative effectiveness) of any drug, biological product, or device (including those drugs, biological products, or devices approved or cleared by the Secretary), except those Phase I clinical trials conducted to test solely the safety of an unapproved drug or unlicensed biological product, or pilot or feasibility studies conducted to confirm the design and operating specifications of an unapproved or not yet cleared medical device.

''(iii) The database may include information for—

''(I) Phase I clinical trials conducted to test solely the safety of an unapproved drug or unlicensed biological product, or pilot or feasibility studies conducted to confirm the design and operating specifications of an unapproved or not yet cleared medical device with the consent of the responsible person; and

''(II) clinical trials of other health-related interventions with the consent of the responsible person.

''(iv) The information to be included in the database under this subparagraph shall include the following:

''(I) Descriptive information, including—

''(aa) a brief title;

''(bb) the drug, biological product or device to be tested;

''(cc) a trial description in lay terminology;

''(dd) the trial phase;

''(ee) the trial type;

''(gg) the trial purpose;

''(hh) the estimated completion date for the trial; and

''(ii) the study sponsor and the study funding source.

''(II) A description of the primary and secondary clinical outcome measures to be examined in the trial, the time at which the outcome measures will be assessed, and the dates and details of any revisions to such outcomes.

''(III) The actual completion date of the trial and the reasons for any difference from such actual date and the estimated completion date submitted pursuant to subclause (I)(hh). If the trial is not completed, the termination date and reasons for such termination.

''(IV) A summary of the results of the trial in a standard, non-promotional summary format (such as ICHE3 template form), including the trial design and methodology, results of the primary and secondary outcome measures as described in subclause (II), summary data tables with respect to the primary and secondary outcome measures, including information on the statistical significance or lack thereof of such results.

''(V) Safety data concerning the trial (including a summary of all adverse events specifying the number and type of such events, data on prespecified adverse events, data on serious adverse events, and data on overall deaths).

''(VI) Any publications in peer reviewed journals relating to the trial. If the trial results are published in a peer reviewed journal, the database shall include a citation to and, when available, a link to the journal article.

''(VII) A description of the process used to review the results of the trial, including a statement about whether the results have been peer reviewed by reviewers independent of the trial sponsor.

''(VIII) If the trial addresses the safety, effectiveness, or benefit of a use not described in the approved labeling for the drug, biological product, or device, a statement, as appropriate, displayed prominently at the beginning of the data in the registry with respect to the trial, that the Food and Drug Administration—

''(aa) is currently reviewing an application for approval of such use to determine whether the use is safe and effective;

''(bb) has disapproved an application for approval of such use;

''(cc) has reviewed an application for approval of such use but the application was withdrawn prior to approval or disapproval; or

''(dd) has not reviewed or approved such use as safe and effective.

''(IX) If data from the trial has not been submitted to the Food and Drug Administration, an explanation of why it has not been submitted.

''(X) A description of the protocol used in such trial to the extent necessary to evaluate the results of such trial.

''(4)(A) Not later than 90 days after the date of the completion of the review by the Food and Drug Administration of information submitted by a sponsor in support of a new drug application, or a supplemental new drug application, whether or not approved by the Food and Drug Administration, the Commissioner of Food and Drugs shall make available to the public the full reviews conducted by the Administration of such application.

''(B) Not later than 90 days after the date of the completion of a written consultation on a drug concerning the drug's safety conducted by the Office of Drug Safety, regardless of whether initiated by such Office or outside of the Office, the Commissioner of Food and Drugs shall make available to the public a copy of such consultation in full.

''(C) Nothing in this paragraph shall be construed to alter or amend section 301(j) or section 1905 of title 18, United States Code.

''(D) This paragraph shall supersede section 552 of title 5, United States Code.

''(5) The information described in subparagraphs (A) and (B) of paragraph (3) shall be in a format that can be readily accessed and understood by members of the general public, including patients seeking to enroll as subjects in clinical trials.

''(6) The Secretary shall assign each clinical trial a unique identifier to be included

in the registry and in the database described in subparagraphs (A) and (B) of paragraph (3). To the extent practicable, this identifier shall be consistent with other internationally recognized and used identifiers.

''(7) To the extent practicable, the Secretary shall ensure that where the same information is required for the registry and the database described in subparagraphs (A) and (B) of paragraph (3), a process exists to allow the responsible person to make only one submission.''; and

(5) by adding at the end the following:

''(10) In this section, the term 'clinical trial' with respect to the registry and the database described in subparagraphs (A) and (B) of paragraph (3) means a research study in human volunteers to answer specific health questions, including treatment trials, prevention trials, diagnostic trials, screening trials, and quality of life trials.''.

(b) ACTIONS OF SECRETARY REGARDING CLINICAL TRIALS.—Section 402 of the Public Health Service Act (42 U.S.C. 282) is amended—

(1) by redesignating subsections (k) and (l) as subsections (q) and (r), respectively; and

(2) by inserting after subsection (j), the following:

''(k) FEDERALLY SUPPORTED TRIALS.—

''(1) ALL FEDERALLY SUPPORTED TRIALS.—With respect to any clinical trial described in subsection (j)(3)(B) that is supported solely by a grant, contract, or cooperative agreement awarded by the Secretary, the principal investigator of such trial shall, not later than the date specified in paragraph (2), submit to the Secretary—

''(A) the information described in subclauses (II) through (X) of subsection (j)(3)(B)(iv), and with respect to clinical trials in progress on the date of enactment of the FACT Act, the information described in subclause (I) of subsection (j)(3)(B)(iv); or

''(B) a statement containing information sufficient to demonstrate to the Secretary that the information described in subparagraph (A) cannot reasonably be submitted, along with an estimated date of submission of the information described in such subparagraph.

''(2) DATE SPECIFIED.—The date specified in this paragraph shall be the date that is 1 year from the earlier of—

''(A) the estimated completion date of the trial, as submitted under subsection (j)(3)(B)(vi)(I)(hh); or

''(B) the actual date of the completion or termination of the trial.

''(3) CONDITION OF FEDERAL GRANTS, CONTRACTS, AND COOPERATIVE AGREEMENTS.—

''(A) CERTIFICATION OF COMPLIANCE.—To be eligible to receive a grant, contract, or cooperative agreement from the Secretary for the conduct or support of a clinical trial described in subsection (j)(3)(B), the principal investigator involved shall certify to the Secretary that—

''(i) such investigator shall submit data to the Secretary in accordance with this subsection; and

''(ii) such investigator has complied with the requirements of this subsection with respect to other clinical trials conducted by such investigator after the date of enactment of the FACT Act.

''(B) FAILURE TO SUBMIT CERTIFICATION.—An investigator that fails to submit a certification as required under subparagraph (A) shall not be eligible to receive a grant, contract, or cooperative agreement from the Secretary for the conduct or support of a clinical trial described in subsection (j)(3)(B).

''(C) FAILURE TO COMPLY WITH CERTIFICATION.—If, by the date specified in paragraph (2), the Secretary has not received the information or statement described in paragraph (1), the Secretary shall—

''(i) transmit to the principal investigator involved a notice specifying the information or statement required to be submitted to the Secretary and stating that such investigator shall not be eligible to receive further funding from the Secretary if such information or statement is not submitted to the Secretary within 30 days of the date on which such notice is transmitted; and

''(ii) include and prominently display, until such time as the Secretary receives the information or statement described in paragraph (1), as part of the record of such trial in the database described in subsection (j), a notice stating that the results of such trials have not been reported as required by law.

''(D) FAILURE TO COMPLY WITH NOTICE.—If by the date that is 30 days after the date on which the notice described in subparagraph (C) is transmitted, the Secretary has not received from the principal investigator involved the information or statement required pursuant to such notice, the Secretary may not award a grant, contract, cooperative agreement, or any other award to such principal investigator until such principal investigator submits to the Secretary the information or statement required pursuant to such notice.

''(E) SUBMISSION OF STATEMENT BUT NOT INFORMATION.—

''(i) IN GENERAL.—If by the date specified in paragraph (2), the Secretary has received a statement described in paragraph (1)(B) but not the information described in paragraph (1)(A), the Secretary shall transmit to the principal investigator involved a notice stating that such investigator shall submit such information by the date determined by the Secretary in consultation with such investigator.

''(ii) FAILURE TO COMPLY WITH CERTIFICATION.—If, by the date specified by the Secretary in the notice under clause (i), the Secretary has not received the information described in paragraph (1)(B), the Secretary shall—

''(I) transmit to the principal investigator involved a notice specifying the information required to be submitted to the Secretary and stating that such investigator shall not be eligible to receive further funding from the Secretary if such information is not submitted to the Secretary within 30 days of the date on which such notice is transmitted; and

''(II) include and prominently display, until such time as the Secretary receives the information described in paragraph (1)(B), as part of the record of such trial in the database described in subsection (j), a notice stating that the results of such trials have not been reported as required by law.

''(F) FAILURE TO COMPLY WITH NOTICE.—If by the date that is 30 days after the date on which the notice described in subparagraph (E)(ii)(I) is transmitted, the Secretary has not received from the principal investigator involved the information required pursuant to such notice, the Secretary may not award a grant, contract, cooperative agreement, or any other award to such principal investigator until such principal investigator submits to the Secretary the information required pursuant to such notice.

''(G) RULE OF CONSTRUCTION.—For purposes of this paragraph, limitations on the awarding of grants, contracts, cooperative agreements, or any other awards to principal investigators for violations of this paragraph shall not be construed to include any funding that supports the clinical trial involved.

''(4) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to prevent an investigator other than the investigator described in paragraph (3)(F) from receiving an ongoing award, contract, or cooperative agreement.

''(5) INCLUSION IN REGISTRY.—

''(A) GENERAL RULE.—The Secretary shall, pursuant to subsection (j)(5), include—

''(i) the data described in subsection (j)(3)(A) and submitted under the amendments made by section 4(a) of the FACT Act in the registry described in subsection (j) as soon as practicable after receiving such data; and

''(ii) the data described in clause (I) of subsection (j)(3)(B)(iv) and submitted under this subsection or the amendments made by section 4(a) of the FACT Act in the database described in subsection (j) as soon as practicable after receiving such data.

''(B) OTHER DATA.—

''(i) IN GENERAL.—The Secretary shall, pursuant to subsection (j)(5), include the data described in subclauses (II) through (X) of subsection (j)(3)(B)(iv) and submitted under this section in the database described in subsection (j)—

''(I) as soon as practicable after receiving such data; or

''(II) in the case of data to which clause (ii) applies, by the date described in clause (iii).

''(ii) DATA DESCRIBED.—This clause applies to data described in clause (i) if—

''(I) the principal investigator involved requests a delay in the inclusion in the database of such data in order to have such data published in a peer reviewed journal; and

''(II) the Secretary determines that an attempt will be made to seek such publication.

''(iii) DATE FOR INCLUSION IN REGISTRY.—Subject to clause (iv), the date described in this clause is the earlier of—

''(I) the date on which the data involved is published as provided for in clause (ii); or

''(II) the date that is 18 months after the date on which such data is submitted to the Secretary.

''(iv) EXTENSION OF DATE.—The Secretary may extend the 18-month period described in clause (iii)(II) for an additional 6 months if the principal investigator demonstrates to the Secretary, prior to the expiration of such 18-month period, that the data involved has been accepted for publication by a journal described in clause (ii)(I).

''(v) MODIFICATION OF DATA.—Prior to including data in the database under clause (ii) or (iv), the Secretary shall permit the principal investigator to modify the data involved.

''(6) MEMORANDUM OF UNDERSTANDING.—Not later than 6 months after the date of enactment of the FACT Act, the Secretary shall seek a memorandum of understanding with the heads of all other Federal agencies that conduct clinical trials to include in the registry and the database clinical trials sponsored by such agencies that meet the requirements of this subsection.

''(7) APPLICATION TO CERTAIN PERSONS.—The provisions of this subsection shall apply to a responsible person described in subsections (p)(1)(A)(ii)(II) or (p)(1)(B)(i)(II).

''(l) TRIALS WITH NON-FEDERAL SUPPORT.—

''(1) IN GENERAL.—The responsible person for a clinical trial described in subsection (j)(3)(B) shall, not later than the date specified in paragraph (3), submit to the Secretary—

''(A) the information described in subclauses (II) through (X) of subsection (j)(3)(B)(iv), and with respect to clinical trials in progress on the date of enactment of the FACT Act, the information described in subclause (I) of subsection (j)(3)(B)(iv); or

''(B) a statement containing information sufficient to demonstrate to the Secretary that the information described in subparagraph (A) cannot reasonably be submitted, along with an estimated date of submission

of the information described in such subparagraph.

''(2) SANCTION IN CASE OF NONCOMPLIANCE.—

''(A) INITIAL NONCOMPLIANCE.—If by the date specified in paragraph (3), the Secretary has not received the information or statement required to be submitted to the Secretary under paragraph (1), the Secretary shall—

''(i) transmit to the responsible person for such trial a notice stating that such responsible person shall be liable for the civil monetary penalties described in subparagraph (B) if the required information or statement is not submitted to the Secretary within 30 days of the date on which such notice is transmitted; and

''(ii) include and prominently display, until such time as the Secretary receives the information described in paragraph (1), as part of the record of such trial in the database described in subsection (j), a notice stating that the results of such trials have not been reported as required by law.

''(B) CIVIL MONETARY PENALTIES FOR NONCOMPLIANCE.—

''(i) IN GENERAL.—If by the date that is 30 days after the date on which a notice described in subparagraph (A) is transmitted, the Secretary has not received from the responsible person involved the information or statement required pursuant to such notice, the Secretary shall, after providing the opportunity for a hearing, order such responsible person to pay a civil penalty of $10,000 for each day after such date that the information or statement is not submitted.

''(ii) WAIVERS.—In any case in which a responsible person described in clause (i) is a nonprofit entity, the Secretary may waive or reduce the penalties applicable under such clause to such person.

''(C) SUBMISSION OF STATEMENT BUT NOT INFORMATION.—

''(i) IN GENERAL.—If by the date specified in paragraph (3), the Secretary has received a statement described in paragraph (1)(B) but not the information described in paragraph (1)(A) the Secretary shall transmit to the responsible person involved a notice stating that such responsible person shall submit such information by the date determined by the Secretary in consultation with such responsible person.

''(ii) FAILURE TO COMPLY.—If, by the date specified by the Secretary in the notice under clause (i), the Secretary has not received the information described in paragraph (1)(A), the Secretary shall—

''(I) transmit to the responsible person involved a notice specifying the information required to be submitted to the Secretary and stating that such responsible person shall be liable for the civil monetary penalties described in subparagraph (D) if such information is not submitted to the Secretary within 30 days of the date on which such notice is transmitted; and

''(II) include and prominently display, until such time as the Secretary receives the information described in paragraph (1)(A), as part of the record of such trial in the database described in subsection (j), a notice stating that the results of such trials have not been reported as required by law.

''(D) NONCOMPLIANCE.—

''(i) IN GENERAL.—If by the date that is 30 days after the date on which a notice described in subparagraph (C)(ii)(I) is transmitted, the Secretary has not received from the responsible person involved the information required pursuant to such notice, the Secretary, after providing the opportunity for a hearing, order such responsible person to pay a civil penalty of $10,000 for each day after such date that the information is not submitted.

''(ii) WAIVERS.—In any case in which a responsible person described in clause (i) is a nonprofit entity, the Secretary may waive or reduce the penalties applicable under such clause to such person.

''(E) NOTICE OF PUBLICATION OF DATA.—If the responsible person is the manufacturer or distributor of the drug, biological product, or device involved, the notice under subparagraphs (A)(i) and (C)(ii)(I) shall include a notice that the Secretary shall publish the data described in subsection (j)(3)(B) in the database if the responsible person has not submitted the information specified in the notice transmitted by the date that is 6 months after the date of such notice.

''(F) PUBLICATION OF DATA.—Notwithstanding section 301(j) of the Federal Food, Drug, and Cosmetic Act, section 1905 of title 18, United States Code, or any other provision of law, if the responsible person is the manufacturer or distributor of the drug, biological product, or device involved, and if the responsible person has not submitted to the Secretary the information specified in a notice transmitted pursuant to subparagraph (A)(i) or (C)(ii)(I) by the date that is 6 months after the date of such notice, the Secretary shall publish in the registry information that—

''(i) is described in subsection (j)(3)(B); and

''(ii) the responsible person has submitted to the Secretary in any application, including a supplemental application, for the drug or device under section 505, 510, 515, or 520 of the Federal Food, Drug, and Cosmetic Act or for the biological product under section 351.

''(3) DATE SPECIFIED.—The date specified in this paragraph shall be the date that is 1 year from the earlier of—

''(A) the estimated completion date of the trial, submitted under subsection (j)(3)(B)(vi)(I)(hh); or

''(B) the actual date of completion or termination of the trial.

''(4) USE OF FUNDS.—

''(A) IN GENERAL.—The Secretary shall deposit the funds collected under paragraph (2) into an account and use such funds, in consultation with the Director of the Agency for Healthcare Research and Quality, to fund studies that compare the clinical effectiveness of 2 or more treatments for a disease or condition.

''(B) FUNDING DECISIONS.—The Secretary shall award funding under subparagraph (A) based on a priority list established not later than 6 months after the date of enactment of the FACT Act by the Director of the Agency for Healthcare Research and Quality and periodically updated as determined appropriate by the Director.

''(5) INCLUSION IN REGISTRY.—

''(A) GENERAL RULE.—The Secretary shall, pursuant to subsection (j)(5), include—

''(i) the data described in subsection (j)(3)(A) and submitted under the amendments made by section 4(a) of the FACT Act in the registry described in subsection (j) as soon as practicable after receiving such data; and

''(ii) the data described in clause (I) of subsection (j)(3)(B)(iv) and submitted under this subsection in the database described in subsection (j) as soon as practicable after receiving such data

''(B) OTHER DATA.—

''(i) IN GENERAL.—The Secretary shall, pursuant to subsection (j)(5), include the data described in subclauses (II) through (X) of subsection (j)(3)(B)(iv) and submitted under this section in the database described in subsection (j)—

''(I) as soon as practicable after receiving such data; or

''(II) in the case of data to which clause (ii) applies, by the date described in clause (iii).

''(ii) DATA DESCRIBED.—This clause applies to data described in clause (i) if—

''(I) the responsible person involved requests a delay in the inclusion in the database of such data in order to have such data published in a peer reviewed journal; and

''(II) the Secretary determines that an attempt will be made to seek such publication.

''(iii) DATE FOR INCLUSION IN REGISTRY.—Subject to clause (iv), the date described in this clause is the earlier of—

''(I) the date on which the data involved is published as provided for in clause (ii); or

''(II) the date that is 18 months after the date on which such data is submitted to the Secretary.

''(iv) EXTENSION OF DATE.—The Secretary may extend the 18-month period described in clause (iii)(II) for an additional 6 months if the responsible person demonstrates to the Secretary, prior to the expiration of such 18-month period, that the data involved has been accepted for publication by a journal described in clause (ii)(I).

''(v) MODIFICATION OF DATA.—Prior to including data in the database under clause (ii) or (iv), the Secretary shall permit the responsible person to modify the data involved.

''(6) EFFECT.—The information with respect to a clinical trial submitted to the Secretary under this subsection, including data published by the Secretary pursuant to paragraph (2)(F), may not be submitted by a person other than the responsible person as part of, or referred to in, an application for approval of a drug or device under section 505, 510, 515, or 520 of the Federal Food, Drug, and Cosmetic Act or of a biological product under section 351, unless the information is available from a source other than the registry or database described in subsection (j).

''(m) PROCEDURES AND WAIVERS.—

''(1) SUBMISSION PRIOR TO NOTICE.—Nothing in subsections (k) through (l) shall be construed to prevent a principal investigator or a responsible person from submitting any information required under this subsection to the Secretary prior to receiving any notice described in such subsections.

''(2) ONGOING TRIALS.—A factually accurate statement that a clinical trial is ongoing shall be deemed to be information sufficient to demonstrate to the Secretary that the information described in subsections (k)(1)(A) and (l)(1)(A) cannot reasonably be submitted.

''(3) INFORMATION PREVIOUSLY SUBMITTED.—Nothing in subsections (k) through (l) shall be construed to require the Secretary to send a notice to any principal investigator or responsible person requiring the submission to the Secretary of information that has already been submitted.

''(4) SUBMISSION FORMAT AND TECHNICAL STANDARDS.—

''(A) IN GENERAL.—The Secretary shall, to the extent practicable, accept submissions required under this subsection in an electronic format and shall establish interoperable technical standards for such submissions.

''(B) CONSISTENCY OF STANDARDS.—To the extent practicable, the standards established under subparagraph (A) shall be consistent with standards adopted by the Consolidated Health Informatics Initiative (or a successor organization to such Initiative) to the extent such Initiative (or successor) is in operation.

''(5) TRIALS COMPLETED PRIOR TO ENACTMENT.—The Secretary shall establish procedures and mechanisms to allow for the voluntary submission to the database of the information described in subsection (j)(3)(B) with respect to clinical trials completed prior to the date of enactment of the FACT Act. In cases in which it is in the interest of public health, the Secretary may require that information from such trials be submitted to the database. Failure to comply

with such a requirement shall be deemed to be a failure to submit information as required under this section, and the appropriate remedies and sanctions under this section shall apply.

''(6) TRIALS NOT INVOLVING DRUGS, BIOLOGICAL PRODUCTS, OR DEVICES.—The Secretary shall establish procedures and mechanisms to allow for the voluntary submission to the database of the information described in subsection (j)(3)(B) with respect to clinical trials that do not involve drugs, biological products, or devices. In cases in which it is in the interest of public health, the Secretary may require that information from such trials be submitted to the database. Failure to comply with such a requirement shall be deemed to be a failure to submit information as required under this section, and the appropriate remedies and sanctions under this section shall apply.

''(7) SUBMISSION OF INACCURATE INFORMATION.—

''(A) IN GENERAL.—If the Secretary determines that information submitted by a principal investigator or a responsible person under this section is factually and substantively inaccurate, the Secretary shall submit a notice to the investigator or responsible person concerning such inaccuracy that includes—

''(i) a summary of the inaccuracies involved; and

''(ii) a request for corrected information within 30 days.

''(B) AUDIT OF INFORMATION.—

''(i) IN GENERAL.—The Secretary may conduct audits of any information submitted under subsection (j).

''(ii) REQUIREMENT.—Any principal investigator or responsible person that has submitted information under subsection (j) shall permit the Secretary to conduct the audit described in clause (i).

''(C) CHANGES TO INFORMATION.—Any change in the information submitted by a principal investigator or a responsible person under this section shall be reported to the Secretary within 30 days of the date on which such investigator or person became aware of the change for purposes of updating the registry or the database.

''(D) FAILURE TO CORRECT.—If a principal investigator or a responsible person fails to permit an audit under subparagraph (B), provide corrected information pursuant to a notice under subparagraph (A), or provide changed information under subparagraph (C), the investigator or responsible person involved shall be deemed to have failed to submit information as required under this section and the appropriate remedies and sanction under this section shall apply.

''(E) CORRECTIONS.—

''(i) IN GENERAL.—The Secretary may correct, through any means deemed appropriate by the Secretary to protect public health, any information included in the registry or the database described in subsection (j) (including information described or contained in a publication referred to under subclause (VI) of subsection (j)(3)(B)(iv)) that is—

''(I) submitted to the Secretary for inclusion in the registry or the database; and

''(II) factually and substantively inaccurate or false or misleading.

''(ii) RELIANCE ON INFORMATION.—The Secretary may rely on any information from a clinical trial or a report of an adverse event acquired or produced under the authority of section 351 of this Act or of the Federal Food, Drug, and Cosmetic Act in determining whether to make corrections as provided for in clause (i).

''(iii) DETERMINATIONS RELATING TO MISLEADING INFORMATION.—For purposes of clause (i)(II), in determining whether information is misleading, the Secretary shall use the standard described in section 201(n) of the Federal Food, Drug, and Cosmetic Act that is used to determine whether labeling or advertising is misleading.

''(iv) RULE OF CONSTRUCTION.—This subparagraph shall not be construed to authorize the disclosure of information if—

''(I) such disclosure would constitute an invasion of personal privacy;

''(II) such information concerns a method or process which as a trade secret is entitled to protection within the meaning of section 301(j) of the Federal Food, Drug, and Cosmetic Act;

''(III) such disclosure would disclose confidential commercial information or a trade secret, other than a trade secret described in subclause (II), unless such disclosure is necessary—

''(aa) to make a correction as provided for under clause (i); and

''(bb) protect the public health; or

''(IV) if such disclosure relates to a biological product for which no license is in effect under section 351, a drug for which no approved application is in effect under section 505(c) of the Federal Food, Drug, and Cosmetic Act, or a device that is not cleared under section 510(k) of such Act or for which no application is in effect under section 515 of such Act.

''(v) NOTICE.—In the case of a disclosure under clause (iv)(III), the Secretary shall notify the manufacturer or distributor of the drug, biological product, or device involved—

''(I) at least 30 days prior to such disclosure; or

''(II) if immediate disclosure is necessary to protect the public health, concurrently with such disclosure.

''(8) WAIVERS REGARDING CLINICAL TRIAL RESULTS.—The Secretary may waive the requirements of subsections (k)(1) and (l)(1) that the results of clinical trials be submitted to the Secretary, upon a written request from the responsible person if the Secretary determines that extraordinary circumstances justify the waiver and that providing the waiver is in the public interest or consistent with the protection of public health.

''(n) TRIALS CONDUCTED OUTSIDE OF THE UNITED STATES.—

''(1) IN GENERAL.—With respect to clinical trials described in paragraph (2), the responsible person shall submit to the Secretary the information required under subclauses (II) through (X) of subsection (j)(3)(B)(iv). Failure to comply with this paragraph shall be deemed to be a failure to submit information as required under this section, and the appropriate remedies and sanctions under this section shall apply.

''(2) CLINICAL TRIAL DESCRIBED.—A clinical trial is described in this paragraph if—

''(A) such trial is conducted outside of the United States; and

''(B) the data from such trial is—

''(i) submitted to the Secretary as part of an application, including a supplemental application, for a drug or device under section 505, 510, 515, or 520 of the Federal Food, Drug, and Cosmetic Act or for the biological product under section 351; or

''(ii) used in advertising or labeling to make a claim about the drug, device, or biological product involved.

''(o) DEFINITIONS; INDIVIDUAL LIABILITY.—

''(1) RESPONSIBLE PERSON.—

''(A) IN GENERAL.—In this section, the term 'responsible person' with respect to a clinical trial, means—

''(i) if such clinical trial is the subject of an investigational new drug application or an application for an investigational device exemption, the sponsor of such investigational new drug application or such application for an investigational device exemption; or

''(ii) except as provided in subparagraph (B), if such clinical trial is not the subject of an investigational new drug application or an application for an investigational device exemption—

''(I) the person that provides the largest share of the monetary support (such term does not include in-kind support) for the conduct of such trial; or

''(II) in the case in which the person described in subclause (I) is a Federal or State agency, the principal investigator of such trial.

''(B) NONPROFIT ENTITIES AND REQUESTING PERSONS.—

''(i) NONPROFIT ENTITIES.—For purposes of subparagraph (A)(ii)(I), if the person that provides the largest share of the monetary support for the conduct of the clinical trial involved is a nonprofit entity, the responsible person for purposes of this section shall be—

''(I) the nonprofit entity; or

''(II) if the nonprofit entity and the principal investigator of such trial jointly certify to the Secretary that the principal investigator will be responsible for submitting the information described in subsection (j)(3)(B) for such trial, the principal investigator.

''(ii) REQUESTING PERSONS.—For purposes of subparagraph (A)(ii)(I), if a person—

''(I) has submitted a request to the Secretary that the Secretary recognize the person as the responsible person for purposes of this section; and

''(II) the Secretary determines that such person—

''(aa) provides monetary support for the conduct of such trial;

''(bb) is responsible for the conduct of such trial; and

''(cc) will be responsible for submitting the information described in subsection (j)(3)(B) for such trial;

such person shall be the responsible person for purposes of this section.

''(2) DRUG, DEVICE, BIOLOGICAL PRODUCT.—In this section—

''(A) the terms 'drug' and 'device' have the meanings given such terms in section 201 of the Federal Food, Drug, and Cosmetic Act; and

''(B) the term 'biological product' has the meaning given such term in section 351 of this Act.

''(3) INDIVIDUAL LIABILITY.—

''(A) LIMITATION ON LIABILITY OF INDIVIDUALS.—No individual shall be liable for any civil monetary penalty under this section.

''(B) INDIVIDUALS WHO ARE RESPONSIBLE PERSONS.—If a responsible person under subparagraph (A) or (B) of paragraph (1) is an individual, such individual shall be subject to the procedures and conditions described in subsection (k).''.

(c) AUTHORIZATION OF APPROPRIATIONS.—Section 402 of the Public Health Service Act (42 U.S.C. 282), as amended by this section, is further amended by adding at the end the following:

''(s) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated, such sums as may be necessary to carry out this section.''.

SEC. 4. REVIEW AND APPROVAL OF PROPOSALS FOR RESEARCH.

(a) AMENDMENTS.—Section 492A(a) of the Public Health Service Act (42 U.S.C. 289a–1(a)) is amended—

(1) in paragraph (1)(A), by striking ''unless'' and all that follows through the period and inserting the following: ''unless—

''(i) the application has undergone review in accordance with such section and has been recommended for approval by a majority of

the members of the Board conducting the review;

''(ii) such Board has submitted to the Secretary a notification of such approval; and

''(iii) with respect to an application involving a clinical trial to which section 402(j) applies, the principal investigator who has submitted such application has submitted to the Secretary for inclusion in the registry and the database described in section 402(j) the information described in paragraph (3)(A) and subclause (I) of paragraph (3)(B)(iv) of such section.''; and

(2) by adding at the end the following:

''(3) COST RECOVERY.—Nonprofit entities may recover the full costs associated with compliance with the requirements of paragraph (1) from the Secretary as a direct cost of research.''.

(b) REGULATIONS.—The Secretary of Health and Human Services shall modify the regulations promulgated at part 46 of title 45, Code of Federal Regulations, part 50 of title 21, Code of Federal Regulations, and part 56 of title 21, Code of Federal Regulations, to reflect the amendments made by subsection (a).

SEC. 5. PROHIBITED ACTS.

Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

''(hh)(1) The entering into of a contract or other agreement by a responsible person or a manufacturer of a drug, biological product, or device with an individual who is not an employee of such responsible person or manufacturer, or the performance of any other act by such a responsible person or manufacturer, that prohibits, limits, or imposes unreasonable delays on the ability of such individual to—

''(A) discuss the results of a clinical trial at a scientific meeting or any other public or private forum; or

''(B) publish the results of a clinical trial or a description or discussion of the results of a clinical trial in a scientific journal or any other publication.

''(2) The entering into a contract or other agreement by a responsible person or a manufacturer of a drug, biological product, or device with an academic institution or a health care facility, or the performance of any other act by such a responsible person or manufacturer, that prohibits, limits, or imposes unreasonable delays on the ability of an individual who is not an employee of such responsible person or manufacturer to—

''(A) discuss the results of a clinical trial at a scientific meeting or any other public or private forum; or

''(B) publish the results of a clinical trial or a description or discussion of the results of a clinical trial in a scientific journal or any other publication.''.

SEC. 6. REPORTS.

(a) IMPLEMENTATION REPORT.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the appropriate committees of Congress a report on the status of the implementation of the requirements of the amendments made by section 3 that includes a description of the number and types of clinical trials for which information has been submitted under such amendments.

(b) DATA COLLECTION.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall enter into a contract with the Institute of Medicine for the conduct of a study concerning the extent to which data submitted to the registry under section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)) has impacted the public health.

(2) REPORT.—Not later than 6 months after the date on which a contract is entered into under paragraph (1), the Institute of Medicine shall submit to the Secretary of Health and Human Services a report on the results of the study conducted under such paragraph. Such report shall include recommendations for changes to the registry, the database, and the data submission requirements that would benefit the public health.

Mr. GRASSLEY. Mr. President, earlier today, Senate Bill 470 was introduced. I am pleased to sponsor the Fair Access to Clinical Trials Act of 2005, with Senator DODD. I am co-sponsoring this legislation as part of a sustained effort to restore public confidence in the Federal Government's food and drug safety agency. Enactment of this bill will be a meaningful step toward greater transparency and accountability in clinical trials and the scientific process.

The Food and Drug Administration earned its prized reputation through decades of good work on behalf of the American people. The FDA's drug approval process has long been considered the ''Good Housekeeping Seal of Approval.'' However, the Vioxx disaster and its aftermath have shaken the public's confidence. American consumers demand and deserve assurances that the medicines in their cabinets are safe. The health and safety of the public must be the FDA's first and only concern. Unfortunately, reforms at the FDA are necessary to place that mission front and center once again.

I began my oversight of the FDA last year in response to concerns about the reluctance of the FDA to provide information to the public about the increased suicidal risks for young people taking anti-depressants. Last November, I chaired a groundbreaking hearing on drug safety, the FDA and Vioxx. That hearing and other critical drug safety concerns of the past year highlighted the need for reforms and more stringent oversight of the FDA.

Sometimes congressional scrutiny of agency mismanagement can lead to necessary reforms. Sometimes an agency will act on its own to enhance its credibility. I have been pressing for reforms—both administrative and legislative—to bring about greater responsiveness and transparency at the FDA. The risks and benefits of prescription drugs should be readily available to patients and doctors seeking to make informed decisions.

The FACT Act will expand www.clinicaltrials.gov to create a publicly accessible national data bank of clinical trial information comprised of a clinical trial registry and a clinical trial results database. The legislation will foster transparency and accountability in health-related intervention research and development and ensure that the scientific community and the general public have access to basic information about clinical trials. Importantly, the FACT Act will maintain clinicaltrials.gov as a registry for patients and physicians seeking information about ongoing clinical trials for serious or life-threatening diseases and conditions. The legislation will also prevent companies from withholding clinically important information about their products.

The FACT Act will maintain a clinical trial registry accessible to patients and health care practitioners seeking information related to ongoing clinical trials for serious or life-threatening diseases and conditions; establish a clinical trials results database of all publicly and privately funded clinical trial results regardless of outcome that is accessible to the scientific community, health care practitioners, and members of the public; require the Food and Drug Administration (FDA) to make internal drug approval and safety reviews publicly available; build on the successful model of www.clinicaltrials.gov, which was established in 1997. The web site will continue to be run by the National Library of Medicine at the National Institutes of Health, with assistance from the FDA; apply to clinical trials for drugs, biologics, and medical devices. All trials must be registered in the database in order to obtain approval from a U.S. Institutional Review Board; require that foreign trials that are submitted to the FDA or used in advertising to U.S. physicians be registered in the database at the time of submission; require that researchers promptly disclose the objectives, eligibility criteria, sources of funding, and anticipated timeline of clinical trials. The bill's standards will meet all of the minimum criteria for a trial registry set out by the International Committee of Medical Journal Editors on September 8, 2004; mandate that the results of clinical trials be available to doctors and patients. Recognizing that the peer review process is the best safeguard for scientific accuracy, the bill provides time for researchers to publish their results. The disclosure of important trial results satisfies the recommendation of the American Medical Association; establish strong enforcement mechanisms. The bill will provide for civil monetary penalties of up to $10,000 per day for sponsors who refuse to comply. Monetary penalties will be earmarked for studies that compare clinical therapies; provide authority to audit the completeness and accuracy of the information in the registry; and ensure that the Food and Drug Administration has the authority to correct false or misleading statements about the results of clinical trials.

Later this month I will also introduce legislation to establish an independent office of drug safety in the Food and Drug Administration. Today's legislation is an important step toward reforming the FDA. I urge my colleagues to join me in this effort by cosponsoring this important legislation.

Mr. JOHNSON. Mr. President, today I join several of my colleagues in introducing a very important piece of legislation that will improve access to information about prescription drugs for

patients and their doctors. Today, Senators DODD, GRASSLEY, WYDEN and I are introducing the Fair Access to Clinical Trials Act or FACT Act. I commend my colleagues for their hard work on this legislation. I also thank them for their commitment to ensuring that finally, objective, unbiased information can be put in the hands of consumers and doctors, reducing negative outcomes, improving patient care, and ultimately reducing costs of medications.

In recent months, we have learned that certain prescription drugs on the market today may not be as safe as we once thought. GlaxoSmithKline's antidepressant drug, Paxil, was found to increase the risk of suicide among adolescents. Further investigation of this issue indicated that some manufacturers of antidepressants highlighted positive findings of tests on youngsters, while playing down negative or inconclusive ones. In addition, the arthritis medication, Vioxx, was pulled off the market due to negative study findings, and over 27,000 sudden cardiac deaths and heart attacks may have been caused by this medication.

I find it unacceptable that current law does not require that the results of these studies on Paxil and Vioxx be made readily available to doctors and their patients. It is unacceptable that today, much of the information consumers and doctors rely on to make decisions about the medications they use are based on incomplete information. Patients are often swayed by direct-to-consumer drug advertisements and doctors must rely on the information they learn at drug company sponsored conferences. Access to complete information about prescription drugs is an important consumer issue, and that is why I am introducing this legislation that would require pharmaceutical companies to fully disclose clinical drug trial information in a public database before medications are introduced on the shelves.

Under my legislation, all studies on medicines like Paxil and Vioxx would be listed in a public drug trial registry database. The database would include all the studies, both good and bad, the studies that are conducted after the drug is already on the market, and even the studies that are discontinued. Doctors and patients would have access to all different types of information so they could make a clear decision on which drugs are best for any circumstance.

The drug trial database established under this legislation would be accessible to the public on a governmental Web site. The database will include information about the sponsor of the drug trial, the parameters of the study, and the outcome or results of the trial. Medical professionals ought to have complete information available when prescribing medications, and consumers should be aware of all the effects prescription drugs can have when taken over a period of time. Common sense tells us we need transparency in the prescription drug industry when it comes to the effectiveness of medications, and this database works towards that goal and will help to hold drug companies accountable for their products on the market.

I hope the Senate and House will take up this bill and pass it. It addresses an important consumer right-to-know issue that will help to ensure that patients and doctors have the best, most accurate information at their fingertips when making life-altering medical decisions.

By Mr. LEAHY:

S. 472. A bill to criminalize Internet scams involving fraudulently obtaining personal information, commonly known as phishing; to the Committee on the Judiciary.

Mr. LEAHY. Mr. President, today I am introducing a bill, the Anti-Phishing Act of 2005, which targets a serious threat to the security of the Internet.

Phishing is a rapidly growing class of identity theft scams on the Internet that is causing both short-term losses and long-term economic damage. In the short-term, these scams defraud individuals and financial institutions. Estimated losses from phishing attacks are now in the billions of dollars, and those losses are growing. The short-term losses, however, are just a chapter in a larger story. In the long-term, phishing undermines the public's trust in the Internet. By making consumers uncertain about the integrity of the Internet's complex addressing system, phishing threatens to make us all less likely to use the Internet for secure transactions. If you can't trust where you are on the web, you are less likely to use it for commerce and communications.

Those well versed in popular culture may guess that phishing was named after the phenomenally popular Vermont band, Phish. But phishing over the Internet was in fact named from the sport of fishing, as an analogy for its technique of luring Internet prey with convincing email bait. The ''F'' is replaced by a ''P-H'' in keeping with a computer hacker tradition.

Phishing attacks usually start with emails that are, in Internet jargon, ''spoofed.'' That is, they are made to appear to be coming from some trusted financial institution or commercial entity. The spoofed email usually asks the victim to go to a website to confirm or renew private account information. These emails offer a link that appears to take the victim to the website of the trusted institution. In fact the link takes the victim to a phony website that is visually identical to that of the trusted institution, but is in fact run by the criminal. When the victim takes the bait and sends their account information, the criminal uses it—sometimes within minutes—to transfer the victim's funds or to make purchases. Phishers are the new con artists of cyberspace.

Phishing is on the rise. The Anti-Phishing Working Group reports that the number of new phishing messages climbed at a monthly rate of 38 percent in the last six months of 2004. The number of new phishing websites has climbed 24 percent per month since last August. And phishing attacks are increasingly sophisticated. Early phishing attacks were by novices, but there is now evidence that some attacks are backed by organized crime. Some of the attacks these days also include spyware, a type of software that is secretly installed on the victim's computer to surreptitiously capture account information when the victim visits legitimate websites.

In addition, the Internet faces the threat of ''pharming.'' This insidious crime does not rely on email bait. Rather, it attacks web browsers and the Internet's addressing system. The effect is that even individuals who type a desired Internet destination into their web browser may be redirected to a phony web site, with the same disastrous result as clicking on the phony link in a phishing attack.

Some phishers and pharmers can be prosecuted under wire fraud or identity theft statutes, but often these prosecutions take place only after someone has been defrauded. For most of these criminals, that leaves plenty of time to cover their tracks. It has been reported that the average phishing website is active on the Internet for less than six days. Moreover, the mere threat of these attacks undermines everyone's confidence in the Internet. When people cannot trust that websites are what they appear to be, they will not use the Internet for their secure transactions. Traditional wire fraud and identity theft statutes are not sufficient to respond to phishing and pharming.

The Anti-Phishing Act of 2005 protects the integrity of the Internet in two ways. First, it criminalizes the bait. It makes it illegal to knowingly send out spoofed email that links to sham websites with the intention of committing a crime. Second, it criminalizes the sham websites that are the true scene of both types of crime.

There are, of course, important First Amendment concerns to be protected. The Anti-Phishing Act protects parodies and political speech from being prosecuted as Phishing. We have worked closely with various public interest organizations to ensure that the Anti-Phishing Act does not impinge on the important democratic role that the Internet plays.

To many Americans, phishing and pharming are new words. They are certainly a new form of an old crime. They are also very serious, and we need to act aggressively to keep them from eroding the public's trust in online commerce and communication. I look forward to working with others in the Senate in addressing this growing threat to the Internet with effective and responsible action.

By Ms. CANTWELL (for herself, Mr. BINGAMAN, and Mr. LIEBERMAN):

S. 473. A bill to amend the Public Health Service Act to promote and improve the allied health professions; to the Committee on Health, Education, Labor, and Pensions.

Ms. CANTWELL. Mr. President, the well-being of the U.S. population depends to a considerable extent on having access to high quality health care which, in turn, requires the presence of an adequate supply of health care professionals. The Congress and the President recognized this need when we passed, and President Bush signed, the Nurse Reinvestment Act in the 107th Congress. Just as with nurses, we must also insure an adequate supply of well-prepared allied health professionals. That is why, today, I am introducing the Allied Health Reinvestment Act with my good colleagues, Senator BINGAMAN of New Mexico and Senator LIEBERMAN of Connecticut.

The allied health professions are many. Those recognized in the act include professionals in the areas of: dental hygiene, dietetics/nutrition, emergency medical services, health information management, clinical laboratory sciences/medical technology, cytotechnology, occupational therapy, physical therapy, radiologic technology, nuclear medical technology, rehabilitation counseling, respiratory therapy, and speech-language pathology/audiology. This is not an exhaustive list, as the act will leave to the discretion of the Secretary of HHS additional professions deemed eligible.

Today, many allied health professions are characterized by existing workforce shortages, declining enrollments in academic institutions, or a combination of both factors. The American Hospital Association, AHA, reports vacancy rates of 18 percent among radiology technicians, 10 percent among laboratory technologists, 15.3 percent among imaging technicians, and 12.7 percent among pharmacy technicians. In addition, the AHA indicates that hospitals are having increasing difficulties recruiting these same professionals over the preceding 2-year period.

In my own State of Washington, the Washington State Hospital Association reports vacancy rates of 14.3 percent among ultrasound technologists, 11.3 percent among radiology technicians, and 10.9 percent among nuclear medicine technologists. These vacancy rates have a real effect on the hospitals in my State. When I meet with hospital officials back home, they always tell me how the lack of technicians affects patient care.

The Bureau of Labor Statistics projected that in the period 1998–2008, the United States would need a total of 93,000 new professionals in clinical laboratory science by creating 53,000 new positions and filling the 40,000 existing vacancies. That averages 9,000 openings per year for technicians, and yet academic institutions are producing only 4,990 graduates annually. If these numbers stay constant, we will be short by 43,100 needed technicians in 2008.

According to the American Hospital Association, declining enrollment in health education programs contributes to the critical shortages of health care professionals. Similarly, data from a November 2002 study of 90 institutions by the Association of Schools of Allied Health Professions, ASAHP, shows a 3-year period of decline in enrollment in cardiovascular perfusion technology, cytotechnology, dietetics, emergency medical sciences, health administration, health information management, medical technology, occupational therapy, rehabilitation counseling, respiratory therapy, and respiratory therapy technician programs. As an indication of a worsening situation, data from the 2002–2003 academic year, alone, show that dental hygiene, physician assistant, and speech-language pathology and audiology should be added to this list.

While having an adequate number of health professionals in our country is key to ensuring access to health care for all of us, certainly one of the key populations for whom a healthy supply of health professionals is vitally important for is our senior population.

The U.S. Census Bureau reports that rapid growth of the population age 65 and over will begin in 2011 when the first of the baby boom generation reaches age 65 and will continue for many years. From 1900 to 2000, the proportion of persons 65 and over tripled, going from 4.1 percent to 12.4 percent.

The baby-boom generation's movement into middle age, a period when the incidence of heart attack and stroke increases, will produce a higher demand for therapeutic services. Medical advances now enable more patients with critical problems to survive, but in order to do so and maintain a high quality of life, these patients may need extensive therapy.

Along with the aging of the population came an increase in the number of Americans living with one, and often more than one, chronic condition. Today, it is estimated that 125 million Americans live with a chronic condition, and by 2020 as the population ages, that number will increase to an estimated 157 million, with 81 million of them having two or more chronic conditions. Twenty-five percent of individuals with chronic conditions have some type of activity limitations. Two-thirds of Medicare spending is for beneficiaries with five or more chronic conditions.

Many individuals with chronic conditions rely on family caregivers. Approximately 9 million Americans provide such services, and on the average, they spend 24 hours a week doing so. Caregivers aged 65–74 provide an average of 30.7 hours of care per week and individuals aged 75 and older provide an average of 34.5 hours per week.

Women are more likely than men to have chronic conditions, in part because they have longer life expectancies. These same women are caregivers to other chronically ill persons. In addition, 65 percent of caregivers are female, and of all caregivers, nearly 40 percent are 55 years of age and older.

Physicians report that their training does not adequately prepare them to care for this type of patient by providing education and offering effective nutritional guidance. Those aspects of care can be provided by allied health professionals, but many of them need better preparation to treat and coordinate care for patients with chronic conditions. While much emphasis is placed on curative forms of care, additional efforts must be devoted to slowing the progression of disease and its effects.

One example of the effectiveness of allied health interventions may be illustrated by a study funded by the National Institute on Aging, the National Center for Medical Rehabilitation Research, and the Agency for Health Care Policy and Research—since renamed the Agency for Healthcare Research and Quality. The investigation showed that significant benefits resulted from a 9-month occupational therapy intervention intended to reduce health-related declines urban, multiethnic, independent-living older adults. The majority of study participants, 73 percent, lived alone and 26 percent reported at least one disability. Important health-related benefits attributable to the intervention continued over a 6-month interval in the absence of further treatment.

The bill my colleagues and I introduce today, like the Nurse Reinvestment Act in the 107th Congress, is intended to provide incentives for individuals to seek and complete high quality allied health education and training. Furthermore, the bill will provide additional funding to ensure that such education and training can be provided to allied health students so that the U.S. healthcare industry with have a supply of allied health professionals needed to support the Nation's health care system in this decade and beyond.

The bill offers allied health education, practice, and retention grants. Education grants will be used to expand the enrollment in allied health education programs, especially by underrepresented racial and ethnic minority students, and provide educational opportunities through new technologies and methods, including distance-learning. Practice grants are intended to establish or expand allied health practice arrangements in non-institutional settings to demonstrate methods that will improve access to primary health care in rural areas and other medically underserved communities. Retention grants are intended to promote career advancement for allied health personnel.

Grants will also be made available to health care facilities to enable them to

carry out demonstrations of models and best practices in allied health for the purpose of developing innovative strategies or approaches for retention of allied health professionals. These grants will be awarded to a variety of geographic regions, and to a range of different types and sizes of facilities, including facilities located in rural, urban, and suburban areas.

Furthermore, this bill will give the Secretary of HHS, acting through the Administrator of HRSA, the authority to enter into an agreement with any institution that offers an eligible allied health education program to establish and operate a faculty loan fund to increase the number of qualified allied health faculty. Loans may be granted to faculty who are pursuing a full-time course of study or, at the discretion of the Secretary, a part-time course of study in an advanced degree program.

I am especially proud of the provisions of this legislation regarding the National Health Service Corps program, the brain child of Senator Warren Magnuson of Washington. The NHSC program, of course, encourages students in the health professions such as doctors and dentists to serve in underserved areas throughout our nation in return for loan repayment assistance. And, like the NHSC program, this Allied Health Reinvestment Act will establish a scholarship program that provides scholarships to individuals seeking allied health education in exchange for service by those individuals in rural and other medically underserved areas with allied health personnel shortages.

There are a number of organizations supporting this bill, and I thank them for that support. Among them, the list includes, but is not limited to:

Washington State Hospital Association
Health Work Force Institute (Seattle, WA)
American Association for Respiratory Care
American Association of Community Colleges
American Clinical Laboratory Association
American Dental Hygienists' Association
American Dietetic Association
American Health Information Management Association
American Hospital Association
American Physical Therapy Association
American Society for Clinical Laboratory Science
American Society for Clinical Pathology
American Society of Radiologic Technologists
Association of Academic Health Centers
College of Health Deans
Midwest Regional Deans Group
Myositis Association
National Association of EMS Educators
National Cancer Registrars Association
National Network of Health Career Programs in Two-Year Colleges
Northeast Regional Deans Group

In addition to these organizations, I would also like to express my appreciation to the Association of Schools of Allied Health Professions, ASAHP, for its support of the legislation as well as its ongoing efforts to address the need for allied health professionals and allied health faculty.

ASAHP, founded in 1967, has a membership that includes 108 institutions of higher learning throughout the United States, as well as several hundred individual members. ASAHP publishes a quarterly journal and also conducts an annual survey of member institutions. This annual survey, called the ''Institutional Profile Survey,'' is used for, among other purposes, collecting student application and enrollment data. These data substantiate that there is a pressing need to address existing allied health workforce shortages, which have been further exacerbated by declines in enrollment that have occurred for 4 straight years.

In the survey conducted during the period September–November 2004 for the 2004–2005 class starting in fall 2004, the results from 90 academic institutions indicate that in 16 of the 20 professions studied, available classroom seats were not filled. For example, only 33 percent of enrollment capacity was reached for health information management programs in these schools. Given the emphasis on increasing the use of information technology in health care such as conversion to electronic patient records, that figure is disturbingly low.

Similarly, the survey shows that enrollment levels were low in the following professions: rehabilitation counseling, 44 percent, emergency medical sciences, 66 percent, cytotechnology, 69 percent, and medical technology, 77 percent. Severe workforce shortages already exist in the two laboratory professions and emergency medical personnel will play a key role as first responders in dealing with any bioterrorism incident that might occur.

Using data from the Institutional Profile Survey, as well as the General Accounting Office, U.S. Census Bureau, and other sources, ASAHP has compiled what I believe to be a compelling rationale in its support for the Allied Health Reinvestment Act that Senators BINGAMAN, LIEBERMAN, and I introduce today. I ask unanimous consent that the text of this Rationale for an Allied Health Reinvestment Act from the Association of Schools of Allied Health Professions be printed in the RECORD.

I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

RATIONALE FOR AN ALLIED HEALTH REINVESTMENT ACT

Led by the Association of Schools of Allied Health Professions, a Washington-DC based organization with 108 colleges and universities as members, a coalition of 30 national organizations supports the enactment of an Allied Health Reinvestment Act.

The well-being of the U.S. population depends to a considerable extent on having access to high quality health care, which requires the presence of an adequate supply of competently-prepared allied health professionals. Workforce, demographic, and epidemiologic imperatives are the driving forces behind the need to have such legislation enacted.

THE WORKFORCE IMPERATIVE

Many allied health professions are characterized by existing workforce shortages, declining enrollments in academic institutions, or a combination of both factors. Hospital officials have reported vacancy rates of 18 percent among radiologic technologists and 10 percent among laboratory technologists, plus they indicated more difficulty in recruiting these same professionals than two years prior.

Fitch, a leading global rating agency that provides the world's credit markets with credit opinions, indicates that labor expenses due to personnel shortages will continue to plague hospitals and is the biggest financial concern for that sector because it typically costs up to twice normal equivalent wages to fill gaps with temporary agency help.

The Bureau of Labor Statistics (BLS) projects that in the period 1998–2008, a total of 93,000 positions in clinical laboratory science need to be provided in the form of creating 53,000 new jobs and filling 40,000 existing vacancies. Of the 9,000 openings per year, academic institutions are producing only 4,990 graduates annually. BLS projections in 2004 show that nine of the 10 fastest growing occupations are health or computer (information technology) occupations.

Accredited respiratory therapy programs in 2000 graduated 5,512 students—21% fewer than the 6,062 graduates in 1999. In 2001, the number of graduates from these schools fell another 20% to 4,437. The BLS expects employment of respiratory therapists to increase faster than the average of all occupations, increasing from 21% to 35% through 2010. The aging population and an attendant rise in the incidence of respiratory ailments, including asthma and COPD, and cardiopulmonary diseases drive this demand.

Employment growth in schools will result from expansion of the school-age population and extended services for disabled students. Therapists will be needed to help children with disabilities prepare to enter special education programs.

The American Hospital Association has identified declining enrollment in health education programs as a factor leading to critical shortages of health care professionals. That assessment is buttressed by data from 90 institutions belonging to the Association of Schools of Allied Health Professions. The following professions were unable to reach enrollment capacity over a three-year period: cardiovascular perfusion technology, cytotechnology, dietetics, emergency medical sciences, health administration, health information management, medical technology, occupational therapy, rehabilitation counseling, respiratory therapy, and respiratory therapy technician.

Given the level of anxiety over the possibility of terrorist attacks occurring in this country, in a study released by the General Accounting Office (GAO) on April 8, 2003 that focused on the nation's adequacy of preparedness against bioterrorism, it was reported that shortages in clinical laboratory personnel exist in state and local public health departments, laboratories, and hospitals. Moreover, these shortages are a major concern that is difficult to remedy.

Laboratories play a critical role in the detection and diagnosis of illnesses resulting from exposure to either biological or chemical agents. No therapy or prophylaxis can be initiated without laboratory identification and confirmation of the agent in question. Laboratories need to have adequate capacity and necessary staff to test clinical and environmental samples in order to identify an

agent promptly so that proper treatment can be started and infectious diseases prevented from spreading.

Meanwhile, the U.S population continues to become more racially and ethnically diverse. A health care workforce is needed that better reflects the population they serve. Practitioners must become more attuned to cultural differences in order to facilitate communication and enhance health care quality.

THE DEMOGRAPHIC IMPERATIVE

The U.S. Census Bureau reports that rapid growth of the population age 65 and over will begin in 2011 when the first of the baby-boom generation reaches age 65 and will continue for many years. The larger proportions of the population in older age groups result in part from sustained low fertility levels and from relatively larger declines in mortality at older ages in the latter part of the 20th century. From 1900 to 2000, the proportion of persons 65 and over went from 4.1 percent to 12.4 percent.

In the 20th century, the total population more than tripled, while the 65 years and older population grew more than tenfold, from 3.1 million in 1900 to 35.0 million in 2000.

Among the older population, the cohort 85 years and over increased from 122,000 in 1900 to 4.2 million in 2000. Since 1940, this age group increased at a more rapid rate than 65-to-74 year olds and 75-to-85 year olds in every decade. As a proportion of the older population, the 85 and over group went from being four percent of the older population to 12 percent between 1900 and 2000.

THE EPIDEMIOLOGICAL IMPERATIVE

The baby-boom generation's movement into middle age, a period when the incidence of heart attack and stroke increases, will produce a higher demand for therapeutic services. Medical advances now enable more patients with critical problems to survive. These patients may need extensive therapy.

According to Solucient, a major provider of information for health care providers, profound demographic shifts over the next twenty-five years will result in significant increases in the demand for inpatient acute care services if current utilization patterns do not change. An aging baby-boom generation, increasing life expectancy, rising fertility rates, and continued immigration will undoubtedly increase the volume of inpatient hospitalizations and significantly alter the mix of acute care services required by patients over the next quarter century. Nationwide, demographic changes alone could result in a 46 percent increase in acute care bed demand by 2027. Total acute care admissions could also increase by almost 13 million cases in the next quarter century—a growth of 41 percent from the current number of national admissions. Currently, the aged nationwide account for about 40 percent of inpatient admissions and about 49 percent of beds. By 2027, they could make up a majority of acute care services—51 percent of admissions and 59 percent of beds.

Along with the aging of the population came an increase in the number of Americans living with one, and often more than one, chronic condition. Today, it is estimated that 125 million Americans live with a chronic condition, and by 2020 as the population ages, that number will increase to an estimated 157 million, with 81 million of them having two or more chronic conditions. Twenty-five percent of individuals with chronic conditions have some type of activity limitations. Two-thirds of Medicare spending is for beneficiaries with five or more chronic conditions.

Many individuals with chronic conditions rely on family caregivers. Approximately nine million Americans provide such services, and on the average, they spend 24 hours a week doing so. Caregivers age 65–74 provide an average of 30.7 hours of care per week and individuals age 75 and older provide an average of 34.5 hours per week.

Women are more likely than men to have chronic conditions, in part because they have longer life expectancies. These same women are caregivers to other chronically ill persons. In addition, 65 percent of caregivers are female, and of all caregivers, nearly 40 percent are 55 years of age and older.

Physicians report that their training does not adequately prepare them to care for this type of patient in areas such as providing education and offering effective nutritional guidance. Allied health professionals can provide those aspects of care, but many of them need better preparation to treat and coordinate care for patients with chronic conditions. While much emphasis is placed on curative forms of care, additional efforts must be devoted to slowing the progression of disease and its effects.

S. 473

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Allied Health Reinvestment Act''.

SEC. 2. FINDINGS AND PURPOSE.

(a) FINDINGS.—Congress makes the following findings:

(1) The United States Census Bureau and other reports highlight the increased demand for acute and chronic healthcare services among both the general population and a rapidly growing aging portion of the population.

(2) The calls for reduction in medical errors, increased patient safety, and quality of care have resulted in an amplified call for allied health professionals to provide healthcare services.

(3) Several allied health professions are characterized by workforce shortages, declining enrollments in allied health education programs, or a combination of both factors, and hospital officials have reported vacancy rates in positions occupied by allied health professionals.

(4) Many allied health education programs are facing significant economic pressure that could force their closure due to an insufficient number of students.

(b) PURPOSE.—It is the purpose of this Act to provide incentives for individuals to seek and complete high quality allied health education and training and provide additional funding to ensure that such education and training can be provided to allied health students so that the United States healthcare industry with have a supply of allied health professionals needed to support the health care system of the United States in this decade and beyond.

SEC. 3. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT.

Title VII of the Public Health Service Act (42 U.S.C. 292 et seq.) is amended by adding at the end the following:

''PART G—ALLIED HEALTH PROFESSIONALS

''SEC. 799C. DEFINITIONS.

''In this part:

''(1) ALLIED HEALTH EDUCATION PROGRAM.—The term 'allied health education program' means any postsecondary educational program offered by an institution accredited by an agency or commission recognized by the Department of Education, or leading to a State certificate or license or any other educational program approved by the Secretary. Such term includes colleges, universities, or schools of allied health and equivalent entities that include programs leading to a certificate, associate, baccalaureate, or graduate level degree in an allied health profession.

''(2) ALLIED HEALTH PROFESSIONS.—The term 'allied health professions' includes professions in the following areas at the certificate, associate, baccalaureate, or graduate level:

''(A) Dental hygiene.

''(B) Dietetics or nutrition.

''(C) Emergency medical services.

''(D) Health information management.

''(E) Clinical laboratory sciences and medical technology.

''(F) Cytotechnology.

''(G) Occupational therapy.

''(H) Physical therapy.

''(I) Radiologic technology.

''(J) Nuclear medical technology.

''(K) Rehabilitation counseling.

''(L) Respiratory therapy.

''(M) Speech-language pathology and audiology.

''(N) Any other profession determined appropriate by the Secretary.

''(3) HEALTH CARE FACILITY.—The term 'health care facility' means an outpatient health care facility, hospital, nursing home, home health care agency, hospice, federally qualified health center, nurse managed health center, rural health clinic, public health clinic, or any similar healthcare facility or practice that employs allied health professionals.

''SEC. 799C–1. PUBLIC SERVICE ANNOUNCEMENTS.

''The Secretary shall develop and issue public service announcements that shall—

''(1) advertise and promote the allied health professions;

''(2) highlight the advantages and rewards of the allied health professions; and

''(3) encourage individuals from diverse communities and backgrounds to enter the allied health professions.

''SEC. 799C–2. STATE AND LOCAL PUBLIC SERVICE ANNOUNCEMENTS.

''(a) IN GENERAL.—The Secretary shall award grants to designated eligible entities to support State and local advertising campaigns that are conducted through appropriate media outlets (as determined by the Secretary) to—

''(1) promote the allied health professions;

''(2) highlight the advantages and rewards of the allied health professions; and

''(3) encourage individuals from disadvantaged communities and backgrounds to enter the allied health professions.

''(b) ELIGIBLE ENTITY.—To be eligible to receive a grant under subsection (a), an entity shall—

''(1) be a professional, national, or State allied health association, State health care provider, or association of one or more health care facilities, allied health education programs, or other entities that provides similar services or serves a like function; and

''(2) prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

''SEC. 799C–3. ALLIED HEALTH RECRUITMENT GRANT PROGRAM.

''(a) PROGRAM AUTHORIZED.—The Secretary shall award grants to eligible entities to increase allied health professions education opportunities.

''(b) ELIGIBLE ENTITY.—To be eligible to receive a grant under subsection (a), an entity shall—

''(1) be a professional, national, or State allied health association, State health care provider, or association of one or more

health care facilities, allied health education programs, or other eligible entities that provides similar services or serves a like function; and

''(2) prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

''(c) USE OF FUNDS.—An entity shall use amounts received under a grant under subsection (a) to—

''(1) support outreach programs at elementary and secondary schools that inform guidance counselors and students of education opportunities regarding the allied health professions;

''(2) carry out special projects to increase allied health education opportunities for individuals who are from disadvantaged backgrounds (including racial and ethnic minorities that are underrepresented among the allied health professions) by providing student scholarships or stipends, pre-entry preparation, and retention activities;

''(3) provide assistance to public and nonprofit private educational institutions to support remedial education programs for allied health students who require assistance with math, science, English, and medical terminology;

''(4) meet the costs of child care and transportation for individuals who are taking part in an allied health education program at any level; and

''(5) support community-based partnerships seeking to recruit allied health professionals in rural communities and medically underserved urban communities, and other communities experiencing an allied health professions shortage.

''SEC. 799C–4. GRANTS FOR HEALTH CAREER ACADEMIES.

''(a) IN GENERAL.—The Secretary shall award grants to eligible entities to assist such entities in collaborating to carry out programs that form education pipelines to facilitate the entry of students of secondary educational institutions, especially underrepresented racial and ethnic minorities, into careers in the allied health professions.

''(b) ELIGIBLE ENTITY.—To be eligible to receive a grant under subsection (a), an entity shall—

''(1) be an institution that offers allied health education programs, a health care facility, or a secondary educational institution; and

''(2) prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

''SEC. 799C–5. ALLIED HEALTH EDUCATION, PRACTICE, AND RETENTION GRANTS.

''(a) EDUCATION PRIORITY AREAS.—The Secretary may award grants to or enter into contracts with eligible entities to—

''(1) expand the enrollment of individuals in allied health education programs, especially the enrollment of underrepresented racial and ethnic minority students; and

''(2) provide education through new technologies and methods, including distance-learning methodologies.

''(b) PRACTICE PRIORITY AREAS.—The Secretary may award grants to or enter into contracts with eligible entities to—

''(1) establish or expand allied health practice arrangements in noninstitutional settings to demonstrate methods to improve access to primary health care in rural areas and other medically underserved communities;

''(2) provide care for underserved populations and other high-risk groups such as the elderly, individuals with HIV/AIDS, substance abusers, the homeless, and victims of domestic violence;

''(3) provide managed care, information management, quality improvement, and other skills needed to practice in existing and emerging organized health care systems; or

''(4) develop generational and cultural competencies among allied health professionals.

''(c) RETENTION PRIORITY AREAS.—

''(1) IN GENERAL.—The Secretary may award grants to and enter into contracts with eligible entities to enhance the allied health professions workforce by initiating and maintaining allied health retention programs described in paragraph (2) or (3).

''(2) GRANTS FOR CAREER LADDER PROGRAMS.—The Secretary may award grants to and enter into contracts with eligible entities for programs—

''(A) to promote career advancement for allied health personnel in a variety of training settings, cross training or specialty training among diverse population groups, and the advancement of individuals; and

''(B) to assist individuals in obtaining the education and training required to enter the allied health professions and advance within such professions, such as by providing career counseling and mentoring.

''(3) ENHANCING PATIENT CARE DELIVERY SYSTEMS.—

''(A) GRANTS.—The Secretary may award grants to eligible entities to improve the retention of allied health professionals and to enhance patient care that is directly related to allied health activities by enhancing collaboration and communication among allied health professionals and other health care professionals, and by promoting allied health involvement in the organizational and clinical decision-making processes of a health care facility.

''(B) PREFERENCE.—In making awards of grants under this paragraph, the Secretary shall give preferences to applicants that have not previously received an award under this paragraph and to applicants from rural, underserved areas.

''(C) CONTINUATION OF AN AWARD.—The Secretary shall make continuation of any award under this paragraph beyond the second year of such award contingent on the recipient of such award having demonstrated to the Secretary measurable and substantive improvement in allied health personnel retention or patient care.

''(d) ELIGIBLE ENTITY.—To be eligible to receive a grant under this section, an entity shall—

''(1) be a health care facility, or any partnership or coalition containing a health care facility or allied health education program; and

''(2) prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

''SEC. 799C–6. DEVELOPING MODELS AND BEST PRACTICES PROGRAM.

''(a) AUTHORIZED.—The Secretary shall award grants to eligible entities to enable such entities to carry out demonstration programs using models and best practices in allied health for the purpose of developing innovative strategies or approaches for the retention of allied health professionals.

''(b) ELIGIBLE ENTITY.—To be eligible to receive a grant under this section, an entity shall—

''(1) be a health care facility, or any partnership or coalition containing a health care facility or allied health education program; and

''(2) prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

''(c) DISTRIBUTION OF GRANTS.—In awarding grants under this section, the Secretary shall ensure that grantee represent a variety of geographic regions and a range of different types and sizes of facilities, including facilities located in rural, urban, and suburban areas.

''(d) USE OF FUNDS.—An entity shall use amounts received under a grant under this section to carry out demonstration programs of models and best practices in allied health for the purpose of—

''(1) promoting retention and satisfaction of allied health professionals;

''(2) promoting opportunities for allied health professionals to pursue education, career advancement, and organizational recognition; and

''(3) developing continuing education programs that instruct allied health professionals in how to use emerging medical technologies and how to address current and future health care needs.

''(e) AREA HEALTH EDUCATION CENTERS.—The Secretary shall award grants to area health education centers to enable such centers to enter into contracts with allied health education programs to expand the operation of area health education centers to work in communities to develop models of excellence for allied health professionals or to expand any junior and senior high school mentoring programs to include an allied health professions mentoring program.

''SEC. 799C–7. ALLIED HEALTH FACULTY LOAN PROGRAM.

''(a) ESTABLISHMENT.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, may enter into an agreement with any institution offering an eligible allied health education program for the establishment and operation of a faculty loan fund in accordance with this section (referred to in this section as the 'loan fund'), to increase the number of qualified allied health faculty.

''(b) AGREEMENTS.—Each agreement entered into under this section shall—

''(1) provide for the establishment of a loan fund by the institution offering the allied health education program involved;

''(2) provide for deposit in the loan fund of—

''(A) the Federal capital contributions to the fund;

''(B) an amount provided by the institution involved which shall be equal to not less than one-ninth of the amount of the Federal capital contribution under subparagraph (A);

''(C) any collections of principal and interest on loans made from the fund; and

''(D) any other earnings of the fund;

''(3) provide that the loan fund will be used only for the provision of loans to faculty of the allied health education program in accordance with subsection (c) and for the costs of the collection of such loans and the interest thereon;

''(4) provide that loans may be made from such fund only to faculty who are pursuing a full-time course of study or, at the discretion of the Secretary, a part-time course of study in an advanced degree program; and

''(5) contain such other provisions determined appropriate by the Secretary to protect the financial interests of the United States.

''(c) LOAN PROVISIONS.—Loans from any faculty loan fund established pursuant to an agreement under this section shall be made to an individual on such terms and conditions as the allied health education program may determine, except that—

''(1) such terms and conditions are subject to any conditions, limitations, and requirements prescribed by the Secretary;

''(2) in the case of any individual, the total of the loans for any academic year made by

an allied health education program from loan funds established pursuant to agreements under this section may not exceed $30,000, plus any amount determined by the Secretary on an annual basis to reflect inflation;

''(3) upon completion by the individual of each of the first, second, and third year of full-time employment, as required under the loan agreement, as a faculty member in an allied health education program, the program shall cancel 20 percent of the principal and interest due on the amount of the unpaid portion of the loan on the first day of such employment;

''(4) upon completion by the individual of the fourth year of full-time employment, as required under the loan agreement, as a faculty member in an allied health education program, the program shall cancel 25 percent of the principal and interest due on the amount of the unpaid portion of the loan on the first day of such employment;

''(5) the loan may be used to pay the cost of tuition, fees, books, laboratory expenses, and other reasonable education expenses;

''(6) the loan shall be repayable in equal or graduated periodic installments (with the right of the borrower to accelerate repayment) over the 10-year period that begins 9 months after the individual ceases to pursue a course of study in an allied health education program; and

''(7) such loan shall—

''(A) beginning on the date that is 3 months after the individual ceases to pursue a course of study in an allied health education program, bear interest on the unpaid balance of the loan at the rate of 3 percent per year; or

''(B) subject to subsection (e), if the allied health education program determines that the individual will not complete such course of study or serve as a faculty member as required under the loan agreement under this subsection, bear interest on the unpaid balance of the loan at the prevailing market rate.

''(d) PAYMENT OF PROPORTIONATE SHARE.—Where all or any part of a loan (including interest thereon) is canceled under this section, the Secretary shall pay to the allied health education program involved an amount equal to the program's proportionate share of the canceled portion, as determined by the Secretary.

''(e) REVIEW BY SECRETARY.—At the request of the individual involved, the Secretary may review any determination by an allied health education program under this section.

''SEC. 799C–8. SCHOLARSHIP PROGRAM FOR SERVICE IN RURAL AND OTHER MEDICALLY UNDERSERVED AREAS.

''(a) PROGRAM AUTHORIZED.—The Secretary shall establish a scholarship program (referred to in this section as the 'program') to provide scholarships to individuals seeking allied health education who agree to provide service in rural and other medically underserved areas with allied health personnel shortages.

''(b) PREFERENCE.—In awarding scholarships under this section, the Secretary shall give preference to—

''(1) applicants who demonstrate the greatest financial need;

''(2) applicants who agree to serve in health care facilities experiencing allied health shortages in rural and other medically underserved areas;

''(3) applicants who are currently working in a health care facility who agree to serve the period of obligated service at such facility;

''(4) minority applicants; and

''(5) applicants with an interest in a practice area of allied health that has unmet needs.

''(c) PROGRAM REQUIREMENTS.—

''(1) CONTRACTS.—Under the program, the Secretary shall enter into contracts with eligible individuals under which such individuals agree to serve as allied health professionals for a period of not less than 2 years at a health care facility with a critical shortage of allied health professionals in consideration of the Federal Government agreeing to provide to the individuals scholarships for attendance in an allied health education program.

''(2) ELIGIBLE INDIVIDUALS.—In this subsection, the term 'eligible individual' means an individual who is enrolled or accepted for enrollment as a full-time or part-time student in an allied health education program.

''(3) SERVICE REQUIREMENT.—

''(A) IN GENERAL.—The Secretary may not enter into a contract with an eligible individual under this section unless the individual agrees to serve as an allied health professional at a health care facility with a critical shortage of allied health professionals for a period of full-time service of not less than 2 years, or for a period of part-time service in accordance with subparagraph (B).

''(B) PART-TIME SERVICE.—An individual may complete the period of service described in subparagraph (A) on a part-time basis if the individual has a written agreement that—

''(i) is entered into by the facility and the individual and is approved by the Secretary; and

''(ii) provides that the period of obligated service will be extended so that the aggregate amount of service performed will equal the amount of service that would be performed through a period of full-time service of not less than 2 years.

''(d) REPORTS.—Not later than 18 months after the date of enactment of this part, and annually thereafter, the Secretary shall prepare and submit to the appropriate committees of Congress a report describing the program carried out under this section, including statements regarding—

''(1) the number of enrollees by specialty or discipline, scholarships, and grant recipients;

''(2) the number of graduates;

''(3) the amount of scholarship payments made;

''(4) which educational institution the recipients attended;

''(5) the number and placement location of the scholarship recipients at health care facilities with a critical shortage of allied health professionals;

''(6) the default rate and actions required;

''(7) the amount of outstanding default funds of the scholarship program;

''(8) to the extent that it can be determined, the reason for the default;

''(9) the demographics of the individuals participating in the scholarship program; and

''(10) an evaluation of the overall costs and benefits of the program.

''SEC. 799C–9. GRANTS FOR CLINICAL EDUCATION, INTERNSHIP, AND RESIDENCY PROGRAMS.

''(a) PROGRAM AUTHORIZED.—The Secretary shall award grants to eligible entities to develop clinical education, internship, and residency programs that encourage mentoring and the development of specialties.

''(b) ELIGIBLE ENTITIES.—To be eligible for a grant under this section an entity shall—

''(1) be a partnership of an allied health education program and a health care facility; and

''(2) prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

''(c) USE OF FUNDS.—An eligible entity shall use amounts received under a grant under this section to—

''(1) develop clinical education, internship, and residency programs and curriculum and training programs for graduates of an allied health education program;

''(2) provide support for faculty and mentors; and

''(3) provide support for allied health professionals participating in clinical education, internship, and residency programs on both a full-time and part-time basis.

''SEC. 799C–10. GRANTS FOR PARTNERSHIPS.

''(a) IN GENERAL.—The Secretary shall award grants to eligible entities to enable such entities to form partnerships to carry out the activities described in this section.

''(b) ELIGIBLE ENTITY.—To be eligible to receive a grant under this section, and entity shall—

''(1) be a partnership between an allied health education program and a health care facility; and

''(2) prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

''(c) USE OF FUNDS.—An eligible entity shall use amounts received under a grant under this section to—

''(1) provide employees of the health care facility that is a member of the partnership involved advanced training and education in a allied health education program;

''(2) establish or expand allied health practice arrangements in non-institutional settings to demonstrate methods to improve access to health care in rural and other medically underserved communities;

''(3) purchase distance learning technology to extend general education and training programs to rural areas, and to extend specialty education and training programs to all areas; and

''(4) establish or expand mentoring, clinical education, and internship programs for training in specialty care areas.

''SEC. 799C–11. ALLIED HEALTH PROFESSIONS TRAINING FOR DIVERSITY.

''The Secretary, acting in conjunction with allied health professional associations, shall develop a system for collecting and analyzing allied health workforce data gathered by the Bureau of Labor Statistics, the Health Resources and Services Administration, other entities within the Department of Health and Human Services, the Department of Veterans Affairs, the Center for Medicare & Medicaid Services, the Department of Defense, allied health professional associations, and regional centers for health workforce studies to determine educational pipeline and practitioner shortages, and project future needs for such a workforce.

''SEC. 799C–12. ALLIED HEALTH PROFESSIONS TRAINING FOR DIVERSITY.

''The Secretary shall include schools of allied health among the health professions schools that are eligible to receive grants under this part for the purpose of assisting such schools in supporting Centers of Excellence in health professions education for under-represented minority individuals.

''SEC. 799C–13. REPORTS BY GENERAL ACCOUNTING OFFICE.

''Not later than 4 years after the date of enactment of this part, the Comptroller General of the United States shall conduct an evaluation of whether the programs carried out under this part have demonstrably increased the number of applicants to allied health education programs and prepare and submit to the appropriate committees of Congress a report concerning the results of such evaluation.

''SEC. 799C–14. AUTHORIZATION OF APPROPRIATIONS.

''There is authorized to be appropriated to carry out this part, such sums as may be necessary for each of fiscal years 2006 through 2011.''.

SUBMITTED RESOLUTIONS

SENATE RESOLUTION 67—DESIGNATING THE SECOND WEEK OF MARCH 2005 AS ''EXTENSION LIVING WELL WEEK''

Mr. GRASSLEY (for himself, Mr. ALEXANDER, Mr. ALLARD, Mr. BROWNBACK, Mr. BUNNING, Mr. BURNS, Mr. COCHRAN, Mr. COLEMAN, Ms. COLLINS, Mr. CORNYN, Mr. CRAIG, Mr. DEMINT, Mrs. DOLE, Mr. ENZI, Mr. GRAHAM, Mr. GREGG, Mr. HATCH, Mr. ISAKSON, Mr. LUGAR, Mr. MCCAIN, Ms. MURKOWSKI, Mr. ROBERTS, Mr. SESSIONS, Mr. SMITH, Ms. SNOWE, Mr. TALENT, Mr. THOMAS, Mr. THUNE, Mr. VITTER, Mr. WARNER, Mr. BAUCUS, Mrs. BOXER, Mr. CARPER, Mr. DORGAN, Mr. DURBIN, Mr. FEINGOLD, Mrs. FEINSTEIN, Mr. HARKIN, Mr. INOUYE, Mr. JOHNSON, Mr. KOHL, Mr. LEAHY, Mrs. LINCOLN, Mr. NELSON of Florida, Mr. NELSON of Nebraska, Mr. PRYOR, Mr. SALAZAR, Mr. SCHUMER, Ms. STABENOW, and Mr. JEFFORDS) submitted the following resolution; which was considered and agreed to:

S. RES. 67

Whereas the health and well-being of the family is crucial to the functioning of the Nation and to providing adults and youth with the necessary skills and knowledge to help them achieve the best quality of life possible;

Whereas psychologically, socially, and emotionally strong families provide strength for future generations;

Whereas Extension is a nationwide educational network through the land-grant universities, funded cooperatively through the Department of Agriculture, State governments, and local county, city, and parish governments;

Whereas Extension provides non-biased, research-based information through informal education to help adults, youth, families, farms, businesses, and communities;

Whereas Extension education programs are developed at the grassroots level to meet local needs, and are available in nearly every county and parish in the United States and its territories, from the biggest to the smallest;

Whereas information offered by Extension is provided by scientists and researchers at land-grant universities, and is made practical and relevant by Extension educators working at the local level;

Whereas Extension Family and Consumer Sciences educators are advocates for education for families so that the families might gain skills for a full and productive life; and

Whereas the designation of the second week of March 2005 as ''Extension Living Well Week'' is a fitting tribute to the National Extension Association for Family and Consumer Sciences professionals who provide education that is critical to the quality of life of adults, youth, individuals, and families, including food preparation, food safety, nutrition, financial management, healthy lifestyles, home and work environment and safety, relationship and parenting skills, and much more: Now, therefore, be it

Resolved, That the Senate—

(1) designates the second week of March 2005 as ''Extension Living Well Week'';

(2) encourages the people of the United States to take advantage of the educational opportunities that Extension Family and Consumer Sciences educators provide, education that can help them in raising kids, eating right, spending smart, and living well; and

(3) encourages the people of the United States to conduct appropriate ceremonies, activities, and programs to demonstrate support for Extension Family and Consumer Sciences educators as they teach adults and youth and promote optimum health and wellness of families in the United States through the ''Living Well'' campaign.

SENATE RESOLUTION 68—DESIGNATING MARCH 2, 2005, AS ''READ ACROSS AMERICA DAY''

Ms. COLLINS (for herself, Mr. REED, and Mr. KENNEDY) submitted the following resolution; which was considered and agreed to:

S. RES. 68

Whereas reading is a basic requirement for quality education and professional success, and is a source of pleasure throughout life;

Whereas the people of the United States must be able to read if the United States is to remain competitive in the global economy;

Whereas Congress, through the No Child Left Behind Act of 2001 (Public Law 107–110) and the Reading First, Early Reading First, and Improving Literacy Through School Libraries programs, has placed great emphasis on reading intervention and providing additional resources for reading assistance; and

Whereas more than 40 national associations concerned about reading and education have joined with the National Education Association to use March 2, the anniversary of the birth of Theodor Geisel, also known as Dr. Seuss, to celebrate reading: Now, therefore, be it

Resolved, That the Senate—

(1) designates March 2, 2005, as ''Read Across America Day'';

(2) honors Theodor Geisel, also known as Dr. Seuss, for his success in encouraging children to discover the joy of reading;

(3) encourages parents to read with their children for at least 30 minutes on Read Across America Day in honor of Dr. Seuss and in celebration of reading; and

(4) encourages the people of the United States to observe the day with appropriate ceremonies and activities.

AMENDMENTS SUBMITTED AND PROPOSED

SA 14. Mr. BAYH submitted an amendment intended to be proposed by him to the bill S. 256, to amend title 11 of the United States Code, and for other purposes; which was ordered to lie on the table.

TEXT OF AMENDMENTS

SA 14. Mr. BAYH submitted an amendment intended to be proposed by him to the bill S. 256, to amend title 11 of the United States Code, and for other purposes; which was ordered to lie on the table; as follows:

On page 19, strike line 13, and insert the following:

monthly income.

''(8) Paragraph (2) shall not apply if—

''(A) the debtor, or a member of the debtor's family, is a member of the uniformed services (as defined in section 101(a)(5) of title 10); and

''(B) the filing under this title was a direct result of debts incurred as a result of a reduction of income due to a change of status from civilian employment to service on active duty (as defeind in section 101(d) of title 10) as a member of the uniformed services.''.

On page 146, strike lines 6 through 19, and insert the following:

(b) RESTORING THE FOUNDATION FOR SECURED CREDIT.—Section 1325(b) of title 11, United States Code, is amended by adding at the end the following:

''(3) Section 506 shall not apply to a claim described in subsection (a)(5) under circumstances other than those described in section 707(b)(8)—

''(A) if—

''(i) the creditor has a purchase money security interest securing the debt that is the subject of the claim;

''(ii) the debt was incurred during the 910-day period preceding the date on which the petition was filed; and

''(iii) the collateral for that debt consists of a motor vehicle (as defined in section 30102 of title 49) acquired for the personal use of the debtor; or

''(B) if—

''(i) the debt was incurred during the 1-year period preceding the date on which the petition was filed; and

''(ii) collateral for the debt that is the subject of the claim consists of anything of value other than the collateral described in subparagraph (A)(iii).''.

On page 259, between lines 7 and 8, insert the following:

SEC. 605. GAO STUDY OF CAUSES OF BANKRUPTCY FOR MEMBERS OF THE UNIFORMED SERVICES.

The Comptroller General of the United States shall—

(1) conduct a study of the frequency and causes of bankruptcy by members of the uniformed services; and

(2) provide recommendations to Congress on how to protect members of the uniformed services, and their families, who file for bankruptcy.

NOTICES OF HEARINGS/MEETINGS

COMMITTEE ON RULES AND ADMINISTRATION

Mr. LOTT. Mr. President, I wish to announce that the Committee on Rules and Administration will meet on Tuesday, March 8, 2004, at 9:30 a.m., to examine and discuss S. 271, a bill which reforms the regulatory and reporting structure of organizations registered under Section 527 of the Internal Revenue Code.

For further information regarding this hearing, please contact Susan Wells at the Rules and Administration Committee on 224–6352.

SUBCOMMITTEE ON PUBLIC LANDS AND FORESTS

Mr. CRAIG. Mr. President, I would like to announce for the information of the Senate and the public that a hearing has been scheduled before the Subcommittee on Public Lands and Forests of the Committee on Energy and Natural Resources.

The hearing will be held on Tuesday, March 8, 2004, at 10 a.m. in room SD–366 of the Dirksen Senate Office Building.

The purpose of the hearing is to receive testimony on S. 179, to provide for the exchange of land within the Sierra National Forest, California, and for other purposes; S. 213, to direct the Secretary of the Interior to convey certain Federal land to Rio Arriba County, New Mexico; S. 267, to reauthorize the Secure Rural Schools and Community Self-Determination Act of 2000, and for other purposes; and S. 305, to authorize the Secretary of the Interior to recruit volunteers to assist with or facilitate the activities of various agencies and offices of the Department of the Interior.

Because of the limited time available for the hearing, witnesses may testify by invitation only. However, those wishing to submit written testimony for the hearing record should send two copies of their testimony to the Committee on Energy and Natural Resources, United States Senate, Washington, DC 20510–6150.

For further information, please contact Frank Gladics 202–224–2878 or Amy Millet at 202–224–8276.